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Regulatory Impact Analysis Data Requirements for Registering Pesticides under the Federal Insecticide, Fungicide and Rodenticide Act

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Costs and benefits were evaluated for analyses of five alternative approaches to meeting society's need for information on the health and environmental effects of pesticide chemicals. The analysis was conducted in connection with rulemaking on EPA pre-market data requirements for registration of new pesticides and reregistration of existing pesticides. The approaches varied in terms of govenment intervention from industry to self-certification to strict comprehensive data requirements without waivers. This report was prepared to meet the requirements for analyses specified in Executive Order 12291, the Regulatory Flexibility Act and the Federal Insecticide, Fungicide and Rodenticide Act. Pesticide registration explicitly accepts a trade-off of risks and benefits. A regulatory approach of specifying types of data necessary to support registrations while allowing flexibility in designing protocols was judged to offer the greatest level of net benefits and still achieve the necessary level of protection of human health and environments.

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REGULATORY IMPACT ANALYSIS

DATA REQUIREMENTS FOR REGISTERING PESTICIDES UNDER THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

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Washington, D.C. 20460

August 1982

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Regulatory Impact Analysis
Data Requirements for Registering Pesticides Under The Federal Insecticide, Fungicide and Rodenticide Act

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I. INTRODUCTION

A. Purpose of Analysis

The Environmental Protection Agency through its Office of Pesticide Programs, is charged with the responsibility for regulating pesticide use in the United States. The legal authority for regulating pesticides is established by the Federal Insecticide, Fungicide, and Rodenticide Act, as Amended (FIFRA). FIFRA states, among other things, "no person in any state may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator." FIFRA further states "The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time."

This report presents the results of a Regulatory Impact Analysis of proposed data requirements which have been drafted by Agency staff and are now proposed rulemaking. The registration data requirements must be considered within the context of overall programmatic activities concerning registration of pesticides under FIFRA. The cost and benefits of these data requirements are manifested only by their actual application in registration activities. The programmatic context of the data requirements is presented here along with an overview of compliance costs of other registration activities and program policies.

B. Description of Regulation

The requirement that the Administrator specify the kinds of information required to support registration of pesticides is contained in Section 3(c)(2) of FIFRA. The Environmental Protection Agency has been developing these requirements over a period of years covering several topic areas. Information needed to support the registration of pesticides includes product chemistry, environmental fate and transport, toxicological effects, product performance, labeling, exposure magnitude, good laboratory practices, experimental use applications, and biorational pesticide data requirements. The registration data requirements now include a total of more than 20 areas.

On June 25, 1975, EPA first proposed guidelines for registering pesticides in the United States (40 FR 26802). In response to public comments and further internal Agency review, EPA reproposed in 1978 guidelines subparts on product chemistry, environmental chemistry, hazard evaluation for fish and wildlife, hazard evaluation for humans and domestic animals (Toxicology). An economic impact analysis of the subparts proposed in 1978 was conducted and published in the Federal Register at that time (FR, Sept. 6, 1978, Part II). Comments were again received on the reproposed guidelines. These comments have been considered, and along with additional internal review, revisions to the reproposed guidelines have been made.

In addition to the subparts reproposed in 1978, development of subparts covering other topic areas has been initated by the Agency. Topics additionally include product performance, label requirements, hazard to non-target insects, hazard to non-target plants and micro-organisms, data requirements for experimental use permits, exposure information for reentry purposes, and good laboratory practices.

The Agency is now changing the approach taken in establishing data requirements for registration. Plans now call for issuing non-rulemaking documents describing the methods for generating specific test data. A separate proposed Section 158 to the Code of Federal Regulations containing Subpart B - Registration Data Requirements, is to be issued specifying the test data submittal requirements for the remaining subparts. In effect, Section 158 will establish the specific test data required to support the registration of a product. Registrants or applicants for registration will then be referred to the non-rulemaking documents to be made publically available through the National Technical Information Service (NTIS) for guidance on test methodologies. The regulatory requirements will be keyed to specific product parameters, such as chemical class or formulation type, and to intended use patterns which establish the causation of need for specific test data. Subpart A - General Provisions - will also be issued as a part of Section 158.

The generation and submission of data by applicants desiring to register pesticide products with the EPA is not new and is necessary to EPA in making registration decisions required under the law. Pesticides by design are toxic to biological organisms. The need for understanding the chemical properties, the potentials for exposure, and the toxicological properties of the chemicals used as pesticides is the purpose of the data requirements being proposed by EPA. FIFRA requires the Administrator of EPA make a finding that if a pesticide is registered, its use in accordance with widespread and commonly recognized practices will not generally cause unreasonable adverse effects on the environment. The determination of unreasonable adverse effects on the environment can only be made by having knowledge about the chemical and toxicological properties of the pesticide for which a registration is desired. Making such a finding is a complex review and decision-making process that is beyond the reach of the general population. This is especially true for long term effects which may result from pesticides such as bioaccumulation or chronic health effects. The complexities involved in making determinations of safety for pesticide use moved Congress to regulate pesticides first through the U.S. Department of Agriculture and later the Environmental Protection Agency.

The data submittal requirements have been written to accommodate situations which have been found historically to be typical of intended pesticide registrations. Obviously unique use patterns, physical/chemical properties, or biological properties may make certain requirements unnecessary. Test standards may also require changes in other unusual circumstances. The regulations, taken together with the guidelines, have built in flexibility to cover these situations.

The Agency also intends to issue case-by-case waivers of data requirements for minor uses as stipulated in Section 3(c)(2)(A) of FIFRA. This section of FIFRA provides that in general, data requirements for minor uses be commensurate with extent of use, pattern of use and level of potential exposure for man and the environment. Furthermore, test standards must take into account economic factors such as national volume of use, extent of distribution, and the impact of the cost of meeting the data requirements. In applying these requirements to registration activities, the Agency is continuing to implement a minor use policy which incorporates the requirements of Section 3(c)(2)(A) of FIFRA.

By issuing these regulations and guidance, the Agency intends to inform potential registrants of the types of studies that the Agency considers as necessary for making determinations on the registerability of pesticide products. Specific data requirements represent the current scientific thinking as to the best ways to measure the potential for exposure and the toxicological significance of pesticides to various non-target species including humans. The studies specified are generally accepted internationally as appropriate means to evaluate the risk of toxic chemicals. The Agency also intends that the base of knowledge on the effects of pesticides will be brought up to current scientific standards. The data requirements outlined in the proposed Section 158 are the result of evolution in both identifying problem areas and further developing testing methodologies that would serve as reliable indicators of situations where exposure or toxicological properties of chemicals are likely to cause unreasonable adverse effects.

The potential for interaction between pesticide registrants and the Agency would not be diminished by issuing these regulations. Registrants are required by FIFRA to bear the burden of demonstrating the safety of their products given the intended manner of use for their products. By issuing formal data submittal requirements, the Agency is establishing its position as to the level of effort expected from potential registrants who must by law bear the burden of showing the safety of their products. With the regulations and guidance in place, registrants remain free to interact with Agency staff in explaining their data and applications in the course of the registration process. Written guidance on Agency requirements is useful to the pesticide industry for planning its R&D activities as well as being useful to Agency staff in administering pesticide programs.

C. Requirements for Analysis

This report is intended to meet the requirements of regulatory impact analysis as established by Executive Order No. 12291, the Regulatory Flexibility Act and Section 25 of FIFRA. This document also serves as an input in preparing any analysis required under the Paper Work Reduction Act of 1980.

Executive Order 12291 requires that adequate information concerning the need for, and consequences of, a proposed action be presented. The order requires a finding that potential benefits to society would outweigh the potential costs; and of all the alternative approaches to a given regulatory objective, the proposed action will maximize net benefits to society. In effect, proposed regulations need to undergo a rigorous cost/benefit analysis as permitted by available data. The regulatory impact analysis is to show that alternative means of achieving regulatory goals are available and these have been given proper consideration. Executive Order 12291 also recognizes that legal constraints may play a role in selecting among alternative approaches to achieving regulatory goals.

The Regulatory Flexibility Act requires that Agencies issuing regulations take special note of the impact of proposed regulations on small entities. Analysis requirements under the Regulatory Flexibility Act can and should be combined under the analysis required under Executive Order 12291.

FIFRA, in Section 25, requires that the Administrator of EPA consider such factors as the effects of regulation on production and prices of agricultural commodities, retail food prices and otherwise on the agricultural economy when issuing regulations affecting pesticides.

D. Scope of Analysis

This regulatory impact analysis encompasses the costs, benefits and impacts of five alternative approaches to information generation that supports the FIFRA objective to reduce the adverse human health and environmental effects from pesticide use to acceptable levels while still permitting society to benefit from pesticide use. The core of this analysis is a comparison of the Agency's proposal to issue regulations on information required in support pesticide registration, with alternative approaches in obtaining the necessary information.

The proposed regulation and alternative approaches will be explained in more detail in Section III of this report; briefly the alternative approaches include:

1. Reference Guidelines. The Agency issues non-regulatory guidance as to the current state-of-the-art testing methodologies. Rulemaking on data submittal requirements is not issued. Studies needed to support a pesticide registration are determined by interaction between applicant and Agency reviewers.

2. Regulatory Requirements. The Agency issues regulations on data submittal requirements for the different types of pesticide products and uses to be registered. Waivers are permitted and tiered testing approaches specified where appropriate. Non-regulatory guidance on testing methodologies would be made available by the Agency.

3. Self-Certification. Premarket data are not required to be submitted. Applicants must certify their products will not cause unreasonable adverse effects.

4. Comprehensive Data Requirements. The Agency issues regulations specifying a list of all data requirements that products must fulfill to obtain registration. Waivers and tiered testing are not considered in this approach.

5. Provisional Registration. Registrants are allowed to market their products on a limited basis after having submitted results from "indicator studies" which are short-term and relatively low cost. Full marketing rights would be granted only after all studies, including chronic effects tests, are submitted. Registration of new chemicals and significant new use patterns would be subject to this approach.

The analysis assumes full implementation of these alternatives as specified so as to indicate costs, benefits and impacts on affected sectors or groups. This is done recognizing that, in reality, a combination of two or more of these might be implemented to maximize net benefits to society. Partial implementation of a single alternative is also a possibility, for the same reason. Consideration is also given to the feasibility of government non-regulatory options such as education or training, as well as no government role whatsoever, other than provision of the judicial system to deal with litigation involving impacts of pesticide use resulting in damage claims.

The alternatives selected for analysis are based upon continuing review by pesticide program staff dating back to the first economic impact analysis of the guidelines prepared in 1978. Comments and inputs have been solicited and obtained from various parties and groups prior to and since the 1978 analysis. Consideration has been given the submissions received by Vice President Bush in response to his request for input by the Task Force on Regulatory Relief. Several submissions relate to the Pesticide Program and the guidelines or data requirements initiative in particular. Although a separate evaluation and response will be made concerning the comments received by the Task Force in general, this analysis is designed to relate to the concerns expressed about data requirements and corresponding suggestions.

The guidelines subparts which correspond to various data requirements are in varying states of development. Data submittal requirements with the largest cost factors are now in approximately final form and the associated costs can be estimated quite accurately. There are other subparts where the related data submittal requirements are more subject to change, but requirements are well enough defined to allow prediction of impacts. The less well defined requirements generally call for less costly studies. Specific changes in data data guidance after this time in the near term are not likely to substantially alter the results of this impact analysis of all requirements and guidance taken together.

The analysis of the 1978 proposed guidelines indicated that about 1,460 active ingredients were registered at that time. Of this number, about 1,000 active ingredients were contained in products being produced or marketed, and the remaining 460 were not in current production. Since 1978, a reregistration program called Registration Standards (RS) has begun with the purpose to reregister all currently registered products. For planning and prioritization, the currently registered active ingredients have been grouped into clusters. The 1,460 active ingredients have been reduced to about 600 active ingredients or active ingredient groupings for which standards are to be written. The reduction from 1,460 to 600 results from several factors including identification of obsolete chemicals no longer produced; grouping together of related salts, esters, acids, etc., of the same active ingredient for which a single data base is necessary under the RS program; and identification of many chemicals that are considered as inert ingredients as opposed to active ingredients.

The 600 active ingredients have been divided into 48 clusters based on similarity of major use patterns. In using this cluster approach in assigning priorities for the RS program, active ingredients which substitute for one another on major use sites will be reviewed and reregistered in approximately the same time period. This approach is thought to be necessary to provide equitable treatment for registrants since reregistration is expected to extend over several years. Otherwise, registrants with chemicals reviewed early in the RS program might be at cost disadvantage with competing registrants' products that might be reviewed at a much later time. Also users might be steered toward a less desirable product because it's labeling had not been modified at the same time. This analysis assumes that reregistration will proceed as now planned.

Under the RS program concept, different scenarios or schedules are possible. The 1978 analysis of the proposed guidelines presented two scenarios based on an assumption of 50 standards per year would be completed. One scenario assumed that each standard would identify the schedule for submission of data to obtain reregistration and that data gaps would be filled some years after the standard was established in interim form. The second scenario assumed the establishment of a program to identify data deficiencies for products before a standard was developed and issued covering those products. EPA would then inform registrants of missing data and require them to submit data when the standard development was undertaken and published. The intention of this early notification to registrants was to expedite initiation of testing that might require years to complete.

Currently, the RS program has shown that 50 standards per year was optimistic in that there has generally been more data requiring review than previously thought. Plans now are to complete 25 to 40 standards per year depending upon available Agency resources.

II. SUMMARY OF FINDINGS

A. Overview

The Environmental Protection Agency through its Office of Pesticide Programs regulates distribution, sale and use of pesticides under authority of FIFRA and FFDCA. Under FIFRA, the Program is responsible for decision-making on applications for registration of new products and new uses of registered products, as well as the reregistration of currently registered products. To this end, FIFRA requires EPA to specify the kinds of information it requires to support the registration of pesticides. EPA has proceeded with the development of regulations and guidance covering the diversity of topic areas pertaining to the evaluation of pesticides for possible unreasonable adverse effects on the environment.

The registration data requirements have been analyzed in accordance with requirements for regulatory impact analysis under Executive Order No. 12291, the Regulatory Flexibility Act, and Section 25 of FIFRA relating to impacts on the agricultural sector of the economy. As established by Executive Order No. 12291, the framework for this analysis is a comparison of the costs and benefits for a range of alternative approaches to achieving a regulatory objective. The objective of this regulation is the generation of sufficient information about pesticides to provide for informed and reasoned decisions to keep the adverse human health and environmental effects from pesticide use to acceptable levels, while still permitting society to benefit from pesticide use.

Numerous market-oriented and regulatory approaches have been considered for achieving the stated regulatory objective. Market-oriented approaches operating in the absence of regulatory authority have been judged unlikely to satisfy the highly-complex requirements of the registration decision process. Pesticides are capable of causing chronic effects which may manifest themselves ten or twenty years after initial exposure. This long lag time generally would not allow those people potentially harmed by pesticides to effectively recover damages from pesticide producers and users.

Several regulatory approaches have been reviewed. Five alternative approaches were selected for detailed analysis of costs and benefits. These approaches were:

#1. Reference Guidelines - The Agency issues non-regulatory guidance. Studies needed to support a pesticide registration are determined from interaction between applicant and Agency reviewers.

#2. Regulatory Requirements - The Agency issues regulations on data submittal requirements. Waivers permitted and tiered testing is employed where appropriate.

#3. Self-Certification - Applicants must certify their products not to cause unreasonable adverse effects. Agency enforces this certification.

#4. Comprehensive Data Requirments - Agency issues regulations specifying a list of data required for all registered pesticide products. Waivers and tiered testing not allowed in this approach.

#5. Provisional Registration - Registrants are allowed to market new chemicals for significantly new use sites on limited basis following submission of short-term studies. Full registration marketing rights to be granted only after all studies, including chronic-effects tests, are submitted.

These alternative approaches have been analyzed to determine their relative cost and benefits. Key findings of the analysis are presented in the remainder of this section of the report. Sections III through X of this report summarize the analysis in greater detail. The complete analysis is reported in a separate document (Cost/Benefit Analysis of Data Requirements for Registering Pesticides under FIFRA, OPP/EPA, May 15, 1982).

B. Need for Regulation

1. Domestic pesticide consumption in the United States totals about 1.2 billion pounds of active ingredient annually, not counting such products as elemental chlorine, sulfur, creosote and other wood preservation materials. Pesticide markets currently exhibit a real growth on the order of only 1 or 2 percent annually. In contrast, pesticide usage had doubled between the early 1960's to the late 1970's, giving an average real growth rate of 5 percent per annum in that time period.

2. The agricultural sector of the economy consumes a majority, about 72 percent, of the 1.2 billion pounds active ingredient consumed annually. The combined industrial/governmental/institutional sector accounts for the second largest share of pesticides consumed, about 21%. Finally, home and garden pesticide use represents about 7% of annual domestic consumption in the United States.

3. Actual and potential exposure of people to pesticides is widespread. A majority of the 2 million commercial farms in the U.S. use pesticides. There are about 40 thousand commercial pesticide

applicators who periodically treat the multitude of structures and facilities in the industrial/governmental/institutional and residential sectors of the economy. An estimated 90% of all households use some pesticides in the home, garden, or yard. The vast majority of the population is potentially exposed to pesticides while applying them, or through contact with residues from past application.

4. Virtually the entire U.S. population is exposed to pesticide residues in food. These residues currently are generally at or below levels established by EPA, and enforced by FDA.

5. Pesticides are by design biological poisons seldom specific as to the time, place and target of their biocidal activity. Pesticides are toxic to broad categories of pests and at the same time acutely and chronically toxic to at least some parts of the nontarget biota, including humans. The long term effects of chronic exposure to pesticides are complex matters with considerable uncertainty as to specific outcomes. Pesticides thus, inherently tend to create opportunity for economic externalities (undesired side effects) which need to be controlled.

6. Given the low probability of demonstrating an actual cause/effect relationship for chronic health hazards associated with pesticide exposure, a pesticide producer's expected cost of future liability lawsuits due to chronic effects from his product is low. Economic theory suggests that, in the absence of regulations, firms might find it irrational to spend a million dollars to examine the chronic toxicity of a pesticide chemical. Similar conclusions can be made about the expense of testing pesticides for other adverse effects, particularly for non-target flora and fauna. As such, market oriented approaches for reducing the potential externalities inherent in pesticides use would be of limited effectiveness unless all pesticide producing firms where absolutely socially responsible.

7. Data requirements in support of pesticide product registrations have evolved through a series of legislative initiatives, regulations, and policy directives over the years, dating back to 1910. As potential health or environmental problems were recognized, data to guide appropriate regulatory responses were required of applicants. Current requirements are enforced under authority of FIFRA, as amended, and the Federal Food, Drug and Cosmetic Act. The burden of proof has been placed by law on pesticide registrants to show that their products will not cause unreasonable adverse effects when applied within commonly accepted use practices.

8. The selection of any one of the five alternative approaches to meeting the Pesticide Program's regulatory directive on information requirements would affect several parameters including timeliness of program activities, program costs, programmatic benefits of reduced hazards to humans and the environment, industry compliance costs, and user impacts.

C. Pesticide Program Impacts

1. Pesticide products are regulated under FIFRA largely through a registration mechanism. The decision to register a product and the accompanying decision on permitted conditions of use are based upon review of data either submitted or cited by a registration applicant.

2. Applications to register new chemical active ingredients have resulted in an average of 14 new chemical registrations per year during the 1970's. All new chemical registrations are required to be supported by test data. In FY 80, 70 submissions of cycles were received with an average of 5 submissions per final acceptance.

3. Applications to amend the registration of current products such as the addition of new sites or making formula changes are also processed by OPP. In FY80, about 2,350 such applications were processed.

4. OPP processes applications for registration of products that are identical or substantially similar to currently registered products. Thousands of such applications are processed annually. Such registrations can, with certain legal restrictions, rely on data previously submitted to the Agency.

5. OPP reviews several hundred special registration requests such as for Experimental Use Permits, Special Local Needs Registrations and Emergency Exemptions. Some of these reviews involve data that would be covered by the registration data requirements and guidelines.

6. Under the amended Federal Food, Drug and Cosmetic Act, EPA establishes tolerances for the maximum levels of pesticide residues allowed in food or feed commodities. Residue chemistry and toxicology data are needed to set tolerances at levels where public health protection will be assured. Several hundred petitions for tolerances and amendments to existing tolerances are received by EPA each year.

7. FIFRA requires EPA to reregister all currently registered products in an expeditious manner updating the decision data bases to satisfy current scientific standards and regulatory policy. All currently registered active ingredients have been organized into 600 groupings for the purpose of reregistration processing under a program entitled Registration Standards. An important outcome of the Registration Standards process is to identify and have filled, gaps in the information available on the potential adverse effects of all registered pesticides. Some of these pesticides were registered more than twenty years ago on the basis of test data generated under even older methodologies and before some chronic effects and enviornmental test data were recognized as required.

8. The Registration Standards program contains as a sub-program a Data Call-In feature. Its goal is to inform registrants of current products that long-term chronic health data are needed for certain

kinds of products and to have these data submitted before the full review of the chemical starts. Registrants are required to show progress in producing these data such that complete data bases from chronic effects testing will be available when a chemical is scheduled for review in the Registration Standards program. Otherwise, a delay of up to four years would ensue after the initial Registration Standards review, if a chronic feeding study, for example, was found to be needed. Although invalid studies may still create delays, the disruption of the Registration Standards program is expected to be lessened by having data call-in.

9. Data requirements to support product registration have impacts because of both the costs of generating data and the time required for generation and review of the data. Historically, the average elapsed time from discovery of a chemical's pesticide activity to commercial registration has trended upward from about 5 years in the 1960's to over 7 years in the latter 1970's. By alternative, the estimated time from original discovery to commercial registration is as follows:

Alternative	Months
#1 - Reference Guidelines	85-95
#2 - Regulatory Requirements	80-90
#3 - Self-Certification	60-80
#4 - Comprehensive Data	100-120
#5 - Provisional Registration	60-80

10. Alternative approaches to data requirements can affect the certainty of the ultimate outcome of product registerability decisions. Alternative #4, comprehensive data requirements, would result in the maximum information. Alternative #1, reference guidelines, and Alternative #2, regulatory requirements would come next in terms of certainty of decision outcomes with Alternative #2 having a slight edge. Alternative #5, provisional registration, would rank next because some use of pesticides would be allowed prior to completing the final data base. Alternative #3, self-certification, would achieve the poorest level of certainty about whether products should or should not be allowed in use. Allowing pesticide use and then finding the need to cancel registrations can lead to economic disruption. For example, 12 major EPA cancellation/suspension decisions in the past have been estimated to cause economic dislocations of $350 million. Additional significant amounts of government and industry resources are required in the litigation that accompanies these adversary actions.

11. OPP's current estimated FY 1982 budget is $62.1 million. Set out below are the budget changes estimated to be necessary if each of the five alternative approaches were in place. Impacts are not significant except for the decrease of about 7 percent for regulatory requirements (#2) and an increase of about 5 percent for provisional registration (#5).

Alternative	Increase or Decrease (-) from Alternative #1 in Millions
#2 - Regulatory Requirements	$ -4.1
#3 - Self-Certification	-0.3
#4 - Comprehensive Data	0.1
#5 - Provisional Registration	3.4

12. Pesticides by design are toxic to living organisms. Non-target species including humans may suffer acutely toxic effects from exposure to pesticides. Various individuals within the population including applicators, mixer/loaders, flaggers, field workers, harvesters, by-standers, and home users of pesticides may encounter different severities and frequency of exposure. Approximately 140 fatalities due to pesticide poisoning occur annually in the U.S. About 50 cases are accidental, the remainder appear to be self-induced. About 2,000 non-fatal poisonings requiring hospitalizations occur annually. Also, records indicate that there are an estimated 30,000 physician-treated non-hospitalized poisonings each year.

13. More importantly pesticides may also produce general types of chronic health effects. The routes of exposure for differing segments of the population are generally the same as for acute effects plus important category of dietary exposure. There is a lack of concensus over chronic health effects but it is recognized that chemical exposure may be a cause even though data are limited with regard to the actual extent of pesticide induced carcinogenicity, teratogenicity, reproductive effects, and mutagencitity.

14. The information requirements under the five alternative approaches analyzed are expected to each have essentially the same outcome with respect to acute pesticide poisonings. For chronic health effects, estimates of the proportion of these effects resulting from pesticide exposure are very tentative. Estimates in the range 0.1% to 0.5% have been made. Improvements in the quality of information about the potential chronic health effects of pesticides can be expected to reduce the annual cost of such effects. Precise measurement of the improvement is however not possible. Conversely, reductions in the stringency of requirements can be expected to increase those health costs.

15. Each of the five alternatives would produce no detectable change in the state of acute health effects attributed to pesticides as compared to current levels. Self-certification could permit more such effects than the others, depending upon how well industry quality assurance programs work and the effectiveness of enforcement. Regulatory programs tend to have less impact on acute health effects. Tests for these effects are generally low cost, firms are quite sensitive to potential liability damage suits because of relative ease in linking cause and effect, and users are more likely to be aware of potential hazards, thus exercising more caution.

16. Pesticide registration programs have more impacts upon chronic human health effects, such as cancer and more subtle effects such as fetal death and birth defects. Alternatives differ as to their effectiveness in detecting and avoiding potential chronic health effects. An ordinal ranking can be constructed as follows:

Alternatives	Relative Order for Potential Cases Avoided
#1	2
#2	2
#3	5
#4	1
#5	4

Relative to Alternatives #1 and #2, reference guidelines and regulatory requirements respectively, comprehensive requirements (#4) would be most effective in avoiding health effects and self-certification (#3) is least effective. provisional registration (#5) also tends to be less effective than Alternatives #1 and #2.

17. Environmental effects are reduced by the current program, and could be reduced further under alternatives #2 and #4. Major problems are more likely under #3. Some temporary, localized, reversible, problems are likely under #5 and there may be permanent effects from a single episode of contamination.

D. Compliance Costs

The summary tables below show that significant data generation compliance costs are involved in all of the alternatives. Also, they show that comprehensive data (#4) tends to have the highest industry test costs while self-certification (#3) tends to have the lowest costs. The other alternatives have costs in an intermediate range. The incremenal costs of changing from the current baseline to the alternative approaches are generally significant for the change to comprehensive data requirements and self-certification.

1. Registration data requirements are defined by testing standards and specific data reporting requirements. Flexibility in the requirements results in variability in the estimates of unit costs for individual studies. Unit costs for various tests were estimated from recent studies of testing costs and from data obtained by Agency staff directly from registrants and testing firms. All cost estimates presented below are in 1980/81 prices.

2. Testing costs for a typical active ingredient would be significantly different for the alternative approaches. The costs are estimated for the alternatives as follows:

Alternative	Food Use Chemicals	Non-Food Use Chemicals
	- - - - - - - - - - Dollars-	- - - - - - - - -
#1	1,811,900 - 2,874,200	364,500 - 704,000
#2	1,811,900 - 2,874,200	364,500 - 704,000
#3	905,950 - 2,874,200	182,250 - 704,000
#4	2,717,850 - 4,311,300	546,750 - 1,056,000
#5	1,358,925 - 2,155,650	273,375 - 528,000

3. Testing costs for an initial typical formulated (end-use) product, are much less than for an active ingredient. Many follow-on formulated products registered would incur much lower costs since previously submitted studies could be cited. By alternative approach, they are estimated as follows:

Alternative	Costs ($)
#1 - Reference Guidelines	24,700 - 66,000
#2 - Regulatory Requirements	24,700 - 66,000
#3 - Self-Certification	12,350 - 33,000
#4 - Comprehensive Data	37,050 - 99,000
#5 - Provisional Registration	18,525 - 49,500

4. The annual direct costs of data requirements will vary with the pace of the Registration Standards program and with Data Call-In. The program is expected to produce at least 25 standards per year, with possibly as many as 40 to 50 standards, if program resources permit. The registration of new products is projectable based on historical data. Using the assumptions of 15 new chemicals registered per year and 25 standards issued per year, the annual direct costs are estimated as follows:

Alternative	Annual Costs --------$Million------ Range
#1 - Reference Guidelines	56.3 - 107.0
#2 - Regulatory Requirements	56.3 - 107.0
#3 - Self-Certification	32.2 - 107.0
#4 - Comprehensive Data	80.9 - 153.9
#5 - Provisional Registration	51.2 - 99.6

5. The five alternative regulatory approaches on data requirements are expected to affect the indirect costs of the pesticide industry. The estimated indirect costs incurred by alternatives are:

Alternative	Annual Costs
	-----$Million----
#1 - Reference Guidelines	27.3
#2 - Regulatory Requirements	27.3
#3 - Self-Certification	31.4
#4 - Comprehensive Data	23.4
#5 - Provisional Registration	27.6

6. Total annual data costs (direct and indirect) of one likely scenario including new registrations (15 new chemicals/yr.) and reregistration (25 standards/yr.) with data call-in are projected as follows:

Alternative	Annual Costs	
	----------$Million----------	
	Range	Midpoint
#1 - Reference Guidelines	83.6-134.3	109.0
#2 - Regulatory Requirements	83.6-134.3	109.0
#3 - Self-Certification	63.6-138.4	101.0
#4 - Comprehensive Data	104.3-177.3	140.8
#5 - Provisional Registration	78.8-127.2	103.0

7. The corresponding changes in costs (direct and indirect) of moving from current practices to the alternative approaches are as follows (25 standards/yr., with data call-in):

Alternative	Difference
	-----$Million------
#1 - Reference Guidelines	0
#2 - Regulatory Requirements	0
#3 - Self-Certification	-8.0
#4 - Comprehensive Data	31.8
#5 - Provisional Registration	-6.0

Alternatives #1 and #2 would not generate any significant cost impacts, as costs would be about the same as under the current program. The current program is most similar to Alternative #1, as efforts have been made in the last several years to move toward implementation of proposed guidelines.

E. Pesticide Producer Impacts

1. Costs for current data requirements of \$1.8-\$2.9 million per major new active ingredient (some active ingredients may require up to \$4.0 million in data) are quite significant but account for only about 3 to 6 percent of total developmental costs (\$50-\$70 million.) Costs of data are accentuated because many of these costs occur early in the R&D cycle and are quite risky.

2. Total industry-wide compliance costs of \$84-\$134 million per year would be equal to about 1-2 percent on sales. Many of these costs would be incurred by firms, as a matter of good business practice even if EPA did not require the data.

3. About 130 firms are the active ingredient manufacturers, of which 30 large-scale firms account for the bulk of the technical grade materials. About 100 small firms produce lower volume and speciality products.

4. The market structure of the basic producing industry can be described as a moderately to highly concentrated oligopoly. Relatively few firms produce the bulk of product and a few products tend to dominate national, regional and local markets for individual site/pest combinations. Individual firms tend to significantly influence supply and prices in the markets in which they compete, as is typical of oligopolistic industries.

5. Structure and behavior of the basic producing industry would be affected most significantly if self-certification (#3) or comprehensive data requirements (#4) were implemented. Self-certification would tend to reduce concentration, reduce entry barriers and stimulate competitive behavior. The opposite would be true with comprehensive data requirements.

6. New pesticide product innovation is heavily dependent upon R&D expenditures, which are concentrated among relatively few firms. Decisions to commit R&D funds are influenced greatly by whether patent rights can help insure profits over a period of years and whether one or more major pesticide markets can be served with the resulting product(s). Issuance of written guidance on test protocols and data submission requirements would improve R&D planning by firms. It would also permit firms to locate chemicals which have undesirable risks factors sooner, thus saving R&D effort.

7. The pesticide producing industry has moderate to high profit rates and a high degree of R&D among major firms. Profit rates, R& D and product prices would decline significantly with self-certification and would increase with comprehensive data requirements. Provisional registration would improve incentives for R&D on new active ingredients by permitting earlier commercialization of products, on a limited basis.

8. Impacts on formulators and small firms would be quite nominal with alternatives #1, #2, and #5, due to minor use policy and waivers for small volume products. Self-certification would help small firms to a degree, but comprehensive data requirements would adversely affect small firms and products due to lack of waivers.

F. Pesticide User Impacts

1. The aggregate increase in the cost of pesticides to all users (assuming all costs are passed on by the manufacturers) would range from a decline of $20 million per year to an increase of $43 million, depending upon which alternative is implemented. Pesticide prices could be changed from minus 0.3 to a plus 0.7 percent, if all costs were passed on to users. Approximately 60 percent of this increase would be sustained by agriculture.

2. Pesticide user prices would be increased by the following percentages by alternatives, if testing costs were all passed on to users, which is likely in the long term.

Alternative	Increase in user prices
	-----Percent-----
#1 - Reference Guidelines	0
#2 - Regulatory Requirements	0
#3 - Self-Certification	-0.3 to 0.1
#4 - Comprehensive Data	0.3 to 0.7
#5 - Provisional Registration	-0.1

3. Users would lose at least some existing small volume products under each alternative, due to costs of maintaining them and/or costs of product liability. Losses would be generally nominal, except for comprehensive data requirements, where many would be lost due to limited data waivers.

4. Overall, under each alternative except comprehensive data requirements, there should be no significant impact on farm prices, production, or the agricultural economy.

G. Aggregrate Economic Impacts

1. The aggregate change in net welfare due to the imposition of data requirements would range from a loss of $34 million to a gain of $16 million per year (excluding pesticide program costs and costs of adverse health/environmental effects). Whereas a substantial portion of the increased pesticide costs would be passed on to final consumers in the agricultural sector, in the non-agricultural sector, most of the increased costs would be absorbed either by the pesticide manufacturers or the users of pesticides in the production of other goods and services for sale to final consumers. The breakout of net welfare changes by sector by alternative is as follows:

Alternative	Net Welfare Impact/Yr		
	Agricultural	Non-ag	Total
	----------$Million----------		
#1 - Reference Guidelines	0	0	0
#2 - Regulatory Requirements	0	0	0
#3 - Self-Certification	+8 to -2	+8 to -1	+16 to -3
#4 - Comprehensive Data	-9 to -18	-8 to -16	-17 to -34
#5 - Provisional Registration	+2 to +3	+3 to +2	+5

2. The above net economic welfare impacts are quite nominal, of limited significance to these sectors in view of their overall size.

3. None of the alternatives would be capable of generating significant economic impacts on macroeconomic variables such as employment, inflation or balance of payments.

H. Benefit/Cost Analysis of Regulatory Alternatives

1. The results of the analysis of impacts the alternatives would have upon pesticide program, producers and users and the economy at large provide the basis for the overall benefit/cost analysis of the alternative, as required by Executive Order 12291. The methods used in benefit/cost analysis and the detailed results are presented in Section IX of this report.

2. The benefit/cost analysis was conducted by summarizing the results of the impact analysis in terms of benefits and costs of the alternatives. All qualitative and quantitative impacts were not uniformly amenable of being monetized, so that net benefits could be estimated in dollar terms. Because of this, a benefit/cost rating framework was used as a proxy for benefits and costs.

3. The rating framework provides 100 rating points each for benefits and costs. The points are awarded to the alternatives on the basis of their merits and the importance attached to the various factors (criteria) of program performance (i.e. types of benefits and costs). Once benefit and cost ratings were determined, differences and ratios were computed as basis for judging the relative merits of the alternatives on the basis of benefit and cost criteria. The summary results of the benefit/cost rating analysis are presented in Table II-1.

4. Self-certification had by far the lowest net benefit rating and rating ratio, thus giving it the lowest overall rating of the alternatives. Regulatory guidelines had the highest net benefit rating and ratio, far above the other alternatives. Provisional registration was a relatively close second to regulatory requirements followed by reference guidelines, comprehensive requirements and finally, self-certification. Cost/benefit rating outcomes were computed for some alternative program criteria (weighting factors). The general conclusion to be reached was that the overall rating outcomes were not highly sensitive to differing criteria within the ranges that are consistent with the mandates under FIFRA.

5. The general conclusion to be reached from the analysis is that regulatory requirements is the preferred regulatory approach on the basis of benefit and cost criteria.

6. This analysis is of the five general alternatives applied across all types of chemicals (whether large or small, for food or non-food uses, highly toxic, etc.) and types of registration by program area. It is likely that ultimately, the "best" overall program approach or scenario during a given period of years would be regulatory requirements with minor applications of one or more of the others to capitalize on their features to fit particular needs of particular regulatory situations.

I. Registration Compliance Costs Compared to Overall Compliance Costs

1. Total FIFRA, FFDCA and RCRA compliance costs (to registrants, applicators, users and state agencies) are approximately $232 million per year under the current program, which includes registration data compliance costs along the lines of the reference guidelines (#1). Of this total, about 33-40 percent ($77-92 million) are costs for data generation under FIFRA, including data for RPAR chemicals (about $5.5 million). These FIFRA costs are an amount equal to about 1.3-1.6 percent of the annual user expenditures for pesticides in the U.S. ($5.8 billion in 1980).

Table II-1
Cost/Benefit Rating Summary of Alternative Approaches for Generating Hazard Testing Information on Pesticide Products

	#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self-Certification by Registrants	#4 Comprehensive Requirements	#5 Provisional Registration	Total Rating Points
Total Benefit Rating	21.3	24.2	10	25	19.5	100.0
Total Cost Rating	20.5	20	15.6	26.8	17.1	100.0
Net Benefit Rating	0.8	4.2	-5.6	- 1.8	2.4	-
Ratio of Benefit and Cost Ratings	1.04	1.21	0.64	0.93	1.14	-
Overall Ranking on Basis of Benefit and Cost Criteria	3	1	5	4	2	

Source: Tables IX - 1, 2, 3, and 4.

2. Total FIFRA, FFDCA and RCRA compliance costs are incurred (1980) by groups as follows according to industry function:

Function	Annual Cost $ Million
Basic Production	120
Formulation	42
Application, State Regulation, etc.	70
Total	232

III. NEED FOR REGULATION AND ALTERNATIVE APPROACHES

A. Overview of Pesticide Usage, Exposure and Effects

Large quantities of chemicals, primarily synthetic organic chemicals, are released into the environment as pesticides each year. In 1980, an estimated 1.175 billion pounds (excluding chemicals such as elemental chlorine, creosote, coal tars, elemental sulfur and others) were used in the U.S. (active ingredient basis) (EPA, September, 1980). On a formulated product basis, the total weight of pesticides used was about 3 times the above quantity, or 3.6 billion pounds. Active ingredients equal only about 32% of the total formulated product on the average. The remaining 68% of the total weight of formulated products consists of diluents, carriers, propellants, and other so-called "inerts."

The pesticide program focuses on the use of active ingredients as they produce potential exposure and risk to humans, animals and the environment. "Inerts" are generally not tested and regulated as intensively as active ingredients but do, in some instances, present risk potential to man and the environment. Some very significant problems have been identified with respect to contaminants in formulated pesticide products such as the "dioxin" problem. A large number of products contain at least at low level dioxins, which are among the most toxic of organic compounds.

Agricultural uses of pesticides account for more than 70% of total pesticide use in the United States (846 million pounds or 72% of the total in 1980). This equals about 2.3 billion pounds on a formulated product basis. The usage of pesticides in agriculture results in residues in feed and food products produced on farms which causes human exposure when food is consumed. Farm pesticide usage also produces exposure potential to farm applicators of pesticides, families living on farms and environmental components in rural areas. Pesticides are used on a majority of the 2 million commercial farms in the U.S. Farm field workers, numbering 3.8 million in the U.S. (in 1979), are subject to a high degree of exposure to pesticides, primarily through dermal contact with pesticide residues on plant surfaces.

The second ranking category of pesticide use in the U.S. is in the industrial/governmental/institutional sector which accounts for 21% of the total active ingredient (about 247 million pounds in 1980). Most industrial, governmental and institutional buildings, facilities or other sites have pesticides applied to them at least periodically if not annually producing potential exposure to humans and the environment. There are 40 thousand commercial pesticide applicators applying pesticides to structural sites alone. These applicators are subjected to exposure along with associated workers and by-standers or occupants of such sites.

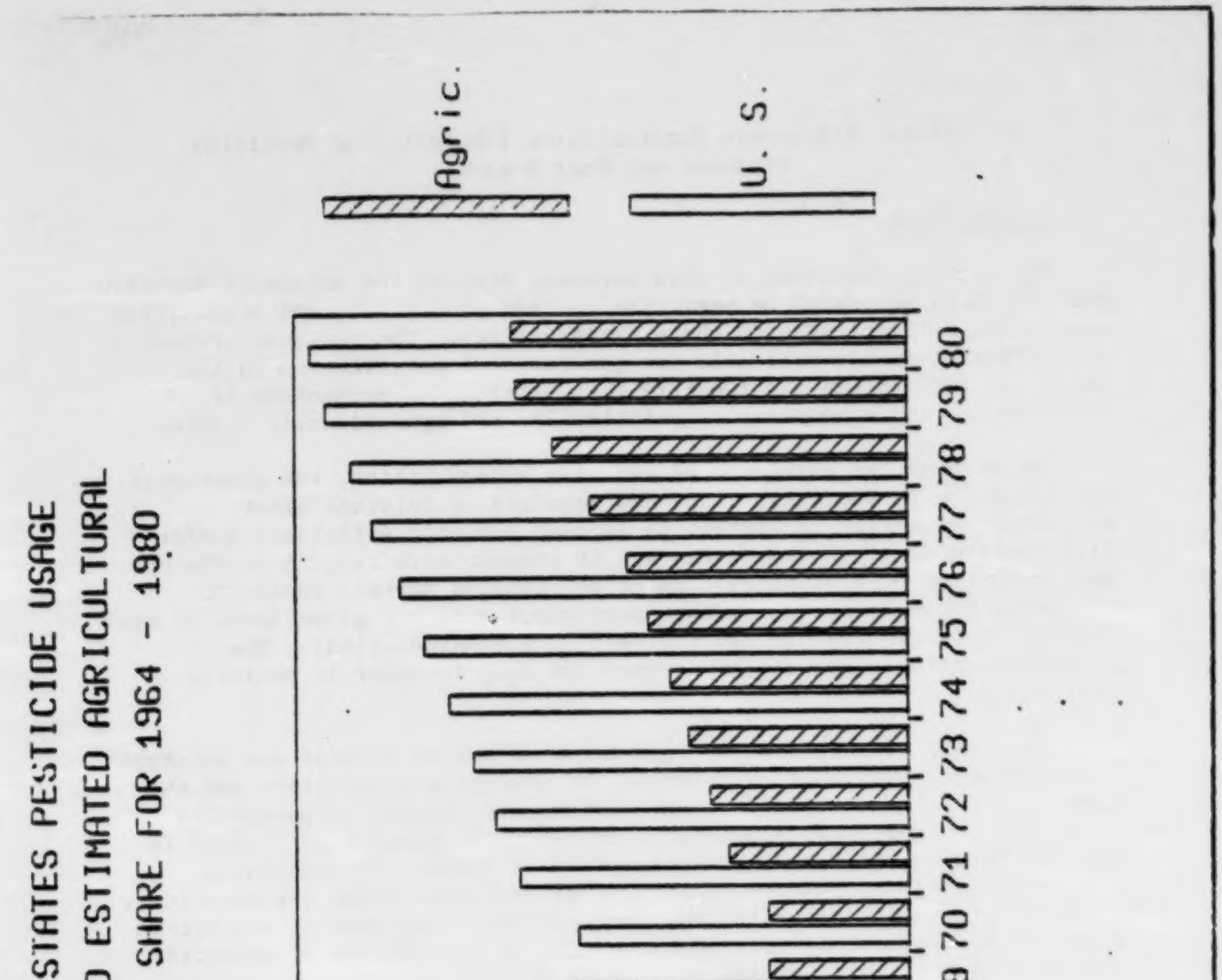
Home and garden usage of pesticides equals about 7% of total usage on an active ingredient basis (82 million pounds in 1980) (EPA, September, 1980). About 90% of U.S. households use pesticides in house, garden or yard based on an EPA study for 1976-77 (EPA, July, 1980). About 84% of households use pesticides in the house and about 21% of households use them in the garden and about 39% use pesticides in the yard.

Pesticide applications in the home by the homeowner or his family tend to be somewhat risker than used for other uses because the homeowner tends to be less proficient in the handling of pesticides and because of the potential for exposure to other persons in the home, particularly children. Historically, there have been several thousand pesticide poisonings per year. As many as 14,000 individuals may be non-fatally poisoned by pesticides in a given year, 6,000 seriously enough to require hospitalization (EPA, May, 1974) (OPP Strategy, page 3). Each year between 100 and 200 deaths occur from pesticide poisonings (including a number of suicides and homicides).

The EPA 1976-77 household survey indicated that approximately 2.5 million households had members of their households who experienced dizziness, headache, nausea or vomiting after using pesticides (3% of total). Most of these (more than 90%) were not severe adverse affects related to pesticide use and were not treated by a physician. These data are indications of only acute exposure and effects from pesticides in the household. Chronic effects are much longer term in nature and less subject to estimation, certainly by survey techniques. Further discussion of chronic as well as acute exposure to pesticides will be presented later in this report.

The trend is for increased usage of pesticides in the United States, although growth is not likely to continue at the rapid rate of the 1960's and 70's. Since the early 1960's, total pesticide usage has about doubled (Figure III-1). Most of the increase in usage is due to expanded agricultural usage, which nearly tripled since 1964. Non-agricultural usage has not shown a consistent tendancy to increase in absolute or percentage terms since the mid-1960's. During the last few years, the growth rate on agricultural use of pesticides has slowed somewhat due to economic conditions and the influence of improved pest management programs resulting in more efficient application of pesticides and alternative non-chemical controls of pests.

A key aspect to exposure and hazards of pesticides is that the chemicals are generally designed as biological poisons, designed to kill or repel biological entities where the mode of action is seldom specific as to the time, place and target of the chemical activity. Pesticides are designed to be acutely toxic to animals, plants and other lower life forms and at the same time are likely to be acutely if not chronically toxic to at least some part of the biota that is nontarget. Long term effects of the chronic exposure of human, animal and other environmental components to pesticides becomes a matter of considerable uncertainty. There are many possibilities for chemical/toxicological interactions between pesticides and living organisms, particularly those resulting from long-term low dosage exposure. The pesticide regulatory program is mandated to deal with such uncertainties and accept only reasonable risks while permitting the benefits to users and the economy generally from the application of pesticides.



UNITED STATES PESTICIDE USAGE
TOTAL AND ESTIMATED AGRICULTURAL
SECTOR SHARE FOR 1964 - 1980

B. Nature of Economic Externalities Inherent from Pesticide Producer and User Behavior

1. Introduction

The next two sections of this document discuss the nature of negative externalities generated by pesticide use and production, and alternative approaches for dealing with these externalities. The sections present a theoretical economic rationale for governmental intervention in the pesticide marketplace and identify what alternative mechanisms of intervention are economically, politically, and operationally viable.

Because of the existence of negative externalities, the government may intervene in the marketplace and regulate or initiate other non-market or market mechanisms to improve economic efficiency and/or distributive equity. Both areas are of concern with respect to the use and production of pesticides. In an unregulated market, pesticide producers would be free to market pesticides with any given level of risk (taking exposure from use and toxicity into consideration). The producer's primary goal is to produce and sell in order to maximize profits.

The costs of pesticide use (in terms of health hazards and environmental damage) are incurred primarily by pesticide applicators and the general population. Pesticide applicators are exposed to pesticides voluntarily through the application process; the general population is exposed involuntarily through consumption of foodstuffs containing pesticide residues, and involuntary dermal and inhalation exposure (e.g. drift) during and after pesticide applications. The general population also incurs the cost of detrimental environmental effects of pesticide use (e.g. non-target, endangered species losses).

Benefits of pesticide production and use accrue to three segments of society. Pesticide producers earn profits, pesticide users increase the productivity of their inputs and earn higher revenues, and consumers are offered goods or services (e.g., agricultural products) at a lower price. Alternatively, consumers may use pesticides as final products (i.e., consumption of pesticide would not be as an input to another productive activity). For example, the use of a household mosquito repellant would be the use of a pesticide as a final product.

Although some pesticides are used as final products, most pesticides are used as an input to the production of other products (e.g. agricultural crops) or services. Under these circumstances, the demand for a pesticide depends upon its price, the prices of all other inputs, and the price of the output. When a pesticide is used as an input to another product, the demand for the pesticide is a derived demand since it depends on the price of the product (e.g., agricultural crop) and is thus derived indirectly from the demand for that product.

2. Economic Efficiency

Economic inefficiencies will occur in the pesticide market due to the existence of negative externalities, imperfect competition, imperfect information, etc. FIFRA attempts to reduce the negative externalities associated with the consumption of pesticides by regulating both the production (e.g., registration process, RPAR process, etc.), and consumption (e.g., certified applicators, enforcement to prevent misuse, etc.) of pesticides.

Given that the negative externalities of pesticide use are not taken fully into consideration by either pesticide users or producers in the pricing of a pesticide in the private marketplace, in an unregulated market, the prices paid for many pesticide products will be too low. In other words, pesticide use potentially exceeds the quantity that would be applied if the market reflected all costs and benefits of pesticide use. This represents less than optimal efficiency in use of resources. An ideal regulatory program would cause amounts and types of pesticides to be used that which would occur if all costs and benefits were considered in the market.

3. Equity

The second issue at hand is one of distributive equity and the reallocation of goods/quality of life among different segments of society. Equity considerations become an issue particularly with respect to the human health effects of pesticide exposure. While pesticide producers, users, and consumers benefit from the use of pesticides, the incidence of the costs are distributed disproportionately throughout the population (in terms of acute and chronic toxic effects such as cancer). Therefore, there will be "victims" from pesticide usage and distributive equity considerations may require their compensation.

Many cause/effect relationships can be directly demonstrated for acute effects of pesticide exposure. In such cases, the victims may be able to prove pesticide producer liability (assuming improper labeling, inadequate warning, etc.) and receive compensation for the detrimental health effects. However, chronic effects such as oncogenicity or teratogenicity may not become evident until 20-30 years after pesticide exposure.

Mutagenic effects may not occur for one or more generations. In such cases, a cause/effect relationship will generally be impossible to demonstrate. Without demonstration of cause and effect, liability of the pesticide producer is not likely to be proven, and victim compensation will not be available.

Distributive equity considerations are of particular concern when the benefits of pesticide use accrue to the current generation and some of the costs are borne by future generations in terms of mutagenic, teratogenic, and ecological effects. In such cases, current consumption of pesticides reallocates goods/quality of life between generations with future generations bearing some of the costs, but none of the benefits.

4. Regulation and the Need for Data Requirements

The current regulatory framework requires submission of data to the Federal government (OPP) by pesticide producers which indicate levels of acute and chronic toxicity of their pesticide products as well as the potential for environmental damage associated with use. The Federal government registers (i.e. regulates) pesticides for specific uses based on performance standards (as opposed to design or input standards) in that the toxicity, exposure, and other detrimental side-effects of the compound, as well as, the expected benefits of the compound, enter the decision criteria for registration.

For example, a pesticide is not denied registration because its LD_{50} exceeds a design standard (i.e. some unacceptable LD_{50} level). Rather, a highly acutely toxic chemical may be registered because it is demonstrated that the actual use of the pesticide will result in negligible exposure, and therefore negligible risk even though the toxicity of the product is high. Required toxicity and exposure data enable pesticide producers and the Federal government to determine what compounds meet the performance standards. The government generally regulates pesticides based on such standards. In the absence of these data requirements, it is reasonable to expect that pesticides would be sold that would result in higher levels of human health and environmental hazard than those which are currently registered.

In fact, in the absence of regulations which require data, a profit maximizing firm may determine that it is economically irrational to perform a battery of laboratory tests to examine chronic toxicity of a pesticide. As earlier discussed, cause/effect relationships can be generally demonstrated for acute human health effects of pesticide exposure, and under certain circumstances pesticide producers could be liable for resultant damages.

However, there is a low probability of demonstrating precise cause/effect relationships for chronic health hazards associated with pesticide exposure. Therefore, the pesticide producer's expected (and in fact actual real world) cost of future liability claims concerning chronic effects of pesticide exposure is also likely to be low. Under such circumstances, it would be economically irrational for a pesticide producer to spend a million dollars to determine chronic toxicity of a chemical when, in fact, chronic toxicity would not positively affect the future net revenues of the firm and could decrease them by uncovering evidence of chronic effects.

C. Alternative General Approaches to Dealing with Pesticide Externalities

1. Introduction

Under the current regulatory process, the Federal government requires submission of health and environmental hazard data for each pesticide active ingredient to ensure that use of the pesticide will not result in unreasonable adverse effects on the environment. Under FIFRA, the burden of proof of the safety of the proposed use of a pesticide is with the applicant for registration. The data requirements and regulatory activities were discussed in the previous section. Alternative mechanisms in addition to or in place of, regulation could be proposed to ensure that, pesticides are used in a manner consistent with social welfare. Conceptually, current data requirements could be lifted and market incentives could be established to improve efficiency of the pesticide market. Alternatively, all regulations could be lifted leaving the court system as the only mechanism to ensure equitable treatment of victims. Educational mechanisms could also be employed to supplement regulatory activites in order to decrease the adverse effects of pesticide use.

Under any of these approaches, direct regulation, market incentives, no regulation (i.e. free market conditions), and reliance on educational mechanisms, the Federal and the State/local governments may carry out independent policies and programs. Under a no regulation Federal approach, it would be expected that State/local governments would substantially increase their regulatory role regarding the production and use of pesticides.

2. Market Incentives

Market incentives, such as taxes and subsidies, can be used to directly affect the production and use of pesticide products. The establishment of a system of taxes and subsidies could be based on the criteria of economic efficiency. In this case, taxes would be established such that the optimal amount of the pesticide would be marketed. Under such a taxing structure, taxes would have to be set for each pesticide product. Due to differing market structures for pesticide products (monopolistic versus competitive), equitable taxes could not be accurately levied. Data requirements for establishment of the tax would include:

- estimation of the demand, private marginal cost, and social marginal cost curves for each pesticide product, and
- determination of the relevant market conditions for each pesticide product.

In many cases, data limitations make estimation of the marginal social costs impossible because the social costs of health and environmental effects cannot be computed.

Even if calculation of taxes/subsidies were administratively possible for each pesticide product, an economically efficient taxing scheme would likely be politically unacceptable.

Since an economically efficient taxing system cannot be implemented, alternative taxing schemes could be developed. Criteria could be established at which tax rates would be imposed and/or incrementally adjusted. The difficulty would be in the selection of the criteria. For example, taxes imposed could be based on the LD_{50} of chemicals; however, this criterion would not take exposure, chronic effect, and environmental damage factors into consideration. Alternative criteria could be identified, but unless the criteria take human exposure by use site and chronic and acute toxicity into consideration as well as aspects of non-human environmental damage, the taxing system may not be as effective in reducing unreasonable adverse effects on the environment as the current regulatory framework.

Furthermore, to develop a taxing scheme based on the relevant exposure, toxicity, and environmental damage criteria would require data similar to that required under current Federal regulations and additional data on the supply and demand function of each chemical product by site. In addition to evaluating the data, the Federal government would also be required to administer a highly complex tax system. This could increase the administrative costs of regulation far above those imposed under the current regulations.

3. Elimination of Federal Pesticide Regulation

All Federal pesticide regulation could be abandoned and the market could operate without Federal intervention. Under such a free market approach, negative externalities would continue to occur. In the absence of regulation, it would be necessary to rely on judicial mechanisms to help ensure that the production and use of pesticides do not result in unreasonable adverse effects. In this regard, judicial mechanisms would primarily be used to compensate victims (individuals and groups of individuals adversely affected by pesticide exposure).

There are major disadvantages associated with total reliance on judicial mechanisms to ensure production and use of "safe" pesticides. The most serious disadvantage is the inability to demonstrate cause/effect relationships for chronic adverse human health effects. In the absence of proof of a cause/effect relationship under current tort law, firms generally would not be held liable for their products and victims would not be compensated.

A further complication would be the absence of required product testing by the pesticide producer. The first step in demonstrating cause/effect relationships is determination of the toxic effects of the chemical. If pesticide producers are not required to generate chronic effects data, and the government became concerned about hazardous effects of certain chemical, this testing function might have to be absorbed by the Federal government. This would shift testing costs from chemical producers (the group obtaining revenues and hence benefits from pesticide sales) to the general taxpaying public.

It would appear that the most effective way for the court system to efficiently reduce large scale negative externalities would be through passage of legislation enabling class-action suits. This would reduce the transaction costs but it still would not resolve the issue of proof of causality.

4. Educational Mechanisms

Educational mechanisms can be evaluated as either an alternative or supplement to Federal regulation of pesticides. By educating pesticide users to adjust their behavior regarding the application of pesticides, the detrimental side-effects of pesticide use and production can be reduced. To the extent that education programs reduce the inefficient use of pesticides (unnecessary prophylactic treatments, inaccurate identification of pest species, inaccurate timing of applications, improper rates of applications, etc.), human, and environmental exposure to pesticides and therefore detrimental effects, can be reduced.

Educational mechanisms can be combined with regulatory mechanisms such as the certified applicator/restricted pesticide program to ensure reductions of detrimental side-effects due to use of the most hazardous compounds. Educational mechanisms will not directly affect the level of data requirements necessary to establish that a compound's use will not result in unreasonable adverse effects on the environment; however, educational mechanisms when combined with regulation, can help minimize adverse effects.

5. State and Local Regulation

Currently, pesticides can be regulated at the Federal, State and local levels. Recent proposals of decentralization and returning Federal powers to the States have been made for many Federal activities. In the case of pesticides, elimination of Federal regulation and leaving all responsibility for pesticide regulation to each state independently is an economically inefficient proposal. The primary disadvantage of State/local regulation is the potential non-uniformity of pesticide product requirements between jurisdictions, resulting in increased administrative costs (governmental) and increased costs to pesticide producers in attempting to comply with a multitude of non-homogenous regulations. Firms may be unwilling for reasons of cost to perform long-term tests to gain entry into a state market. They may view the market as insufficient size in terms of potential revenue.

A powerful example of the unreasonableness of such regulation would be the establishment of pesticide residue tolerances on foodstuffs given the interstate transfer of agricultural commodities in the United States. The administrative costs of each State establishing independent tolerances for all agricultural commodity/pesticide combinations would be much higher than the current centralized regulatory tolerance setting mechanisms. Furthermore, the ability of growers to apply pesticides to their agricultural products and ship them interstate might be severely hampered. Clearly, severe disruptions in the food industry could occur resulting in negative macroeconomic effects.

D. Approach Taken Under FIFRA and Alternatives for Analysis

1. Options to the Current Program

Analysis of alternative approaches to achieving a regulatory objective is specified as mandatory in both Executive Order 12291 and OMB guidance implementing that Order. Four major types of alternatives need to be considered. These include:

- Consequences of having no regulation.
- Major alternatives that might be beyond the specific legislation under which the proposed regulation is being promulgated.
- Alternatives within the scope of specific legislation such as:
    a. alternative stringency levels;
    b. alternative effective dates; and
    c. alternative methods of ensuring compliance.
- Alternative, market-oriented ways of regulation.

With these types of alternative approaches, there are, of course, many specific alternatives. The analysis of a regulation includes the identification of reasonable approaches which are to be the subject of more detailed cost and benefit analyses.

Concerning the "no regulation alternative", the previous discussion of the need for regulation has detailed the theoretical reasons why the marketplace would not operate efficiently to internalize the social costs of pesticide use. Briefly, the long lag time between exposure and the manifestation of chronic effects would make it difficult if not impossible to establish a direct cause and effect relationship that would be necessary for establishing liability. The information requirements needed in an efficiently functioning market do not exist with respect to pesticide effects.

There are alternative regulatory approaches outside the scope of FIFRA to ensure that adequate information on the effects of pesticides are generated. A key feature of FIFRA, as amended, is that the Administrator is required to make a finding that a pesticide will not cause unreasonable adverse effects. In essence, the applicant for registration must shoulder the burden of proving to the Agency that their product can be used within acceptable levels of risk. If the enabling legislation were provided, the opposite philosophy might be tried. Applicants could be required to self-certify to the Agency that their products would not cause unreasonable adverse effects on humans or the environment. The Agency could disallow or limit use only if it had evidence to prove that the self-certification from registrants had been incorrect. This option will be more fully described and analyzed in latter sections of this analysis.

The stringency of the requirements is left to the Agency. Two options with differing philosophy as to stringency of requirements will be described and analyzed in this analysis. Briefly, one approach allows for waivers of testing requirements where such waivers can be supported. Additionally, tiered testing requirements are used where scientifically defensible. The other option is to lay out blanket testing requirements for all pesticide chemicals so that all chemicals are subjected to the same testing regimen.

The requirements to have data in support of registration do not lend themselves to options as to effective dates. Once testing requirements are established, they should be factored into the registration process. There can, however, be options as to whether data requirements should be pre-market or post-market. This analysis will consider a provisional registration plan where some limited sales of pesticide products are permitted before all data requirements are met. This approach is described and analyzed in more detail below.

2. Approaches to be Included in Analysis

From the broad guidance from OMB implementing Executive Order 12291, specific alternative approaches have been selected for further analysis of costs and benefits. As noted in Section I, this analysis will cover five such alternatives including:

#1. Reference guidelines;
#2. Regulatory requirements;
#3. Self-certification by registrants;
#4. Comprehensive data requirements;
#5. Provisional registration.

These five alternatives were selected to represent the major types of alternatives which are applicable to the regulatory objective of generating data on the possible adverse effects of pesticides. The five optional approaches will be described below.

a.) Reference Guidelines (#1)

Data requirements are currently formed from the historical merging of advancing scientific knowledge and the precedents estabished by policy in response to newly recognized health or environmental problems related to pesticide use. OPP presently is reviewing and processing registrations or amendments to registration applications. Basic data requirements including toxicity, chemistry, environmental fate, and non-target organism hazards are being generated and submitted by applicants. Applicants tend to have a rather complete understanding of the data required from them to support registration of their products. Firms with existing registrations are more likely to be in position to anticipate data needs. Other applicants rely on interaction with OPP personnel to determine the testing requirements. Both industry and OPP personnel may refer to the basic data requirements listed in regulations issued in 1975 on registration procedures (40FR 28212). Specific guidance for individual registration actions now occurs through interaction between applicants and OPP reviewers as stated above. Different reviewers, in exercising their scientific judgements, may emphasize different aspects of testing requirements. Reviewers make the scientific determinations as to whether an applicant has adequately demonstrated that his product will not cause unreasonable adverse effects on the environment.

Data requirements are also now being identified for the reregistration of currently registered pesticide products. Under the Registration Standards program, pesticide active ingredients are reviewed to determine how well registrations are supported by data. When significant data gaps are identified, the Agency uses its authority under Section 3(c)(2)(B) of FIFRA to require that these data gaps be filled. Another feature of the Registration Standards program is the Data Call-In process. The Agency has begun to inform registrants with pesticides registered on food or feed use chemicals that tests on chronic effects are needed to support those registrations. The Agency again uses its authority under Section 3(c)(2)(B) of FIFRA to require that these studies be done and reports submitted. This option involves continuing the interactive - iterative process for developing necessary risk data.

b.) Regulatory Requirements (# 2)

Issuance of data submission requirements as regulation would serve primarily to make formal the information requirements in support of pesticide registrations. The specific testing requirements for a product would be discernable from the regulations with more limited interaction between registrants and the Agency. Protocols for testing individual chemicals are to be available publicly through the National Technical Information Service (NTIS). Reviews of test submissions would be expedited because common elements recur in information provided across chemicals. Decisionmaking would be expected to improve with the greater consistency in data being submitted for review. Testing performed would be substantially the same as Alternative #1.

c.) Self-Certification by Registrants (#3)

One approach that would require changes in legislation would involve a self-certification from registrants that their products would not cause unreasonable adverse effects. Risk of corporate or personnel liability for adverse pesticide effects would serve to guide the selection of appropriate levels of testing by registrants. The Agency would maintain a strong monitoring and enforcement posture to protect the public against mistakes in judgement and outright fraudulent activity. That is, any intentionally or unintentionally false representations concerning the potential adverse effects of pesticides would need to be dealt with by the Agency. This would represent a significantly different regulatory philosophy as compared to the first two approaches presented. In the first two approaches, the concept is to prevent the use of products that are likely to cause unreasonable levels of risk. In this approach, direct Agency involvement would serve to stop the use of a product only after unreasonable adverse effects were discovered.

d.) Comprehensive Data Requirements (#4)

Pre-marketing data requirements for pesticides serve as inputs for decisions as to the registerability of products. The greater the quantity and quality of data, the more certain the accuracy of the decisions. Studies on the effects of pesticides have evolved into categories of acute or short-term and chronic or long-term studies. One alternative approach to data requirements is to develop a comprehensive list of studies that measure both acute and chronic effects and require that all chemicals be subjected to the same testing scheme where possible. Very limited waivers from requirements would be granted. Also testing would not be done on a tiered basis, i.e., the need to one test would not depend on the results of other studies.

The comprehensive testing requirements would be based on the theory that the probability of not identifying a potential adverse effect should be kept at a minimum. Hence, long term studies for all chemicals would be required. The full complement of studies would be the same as for Alternative #2 without use of tiered approaches or waivers.

e.) Provisional Registration (#5)

The last approach to be considered in this analysis is to offer a provisional registration that divides information requirements into pre-marketing and post-marketing sets. This approach would require a statutory change. The philosophy behind this approach is that limited sales of a pesticide would be allowed based on a limited data base. If broader sales were desired, then complete information requirements would be imposed. Products could therefore begin generating revenues while long-term chronic studies were being performed. The basic features of provisional registration are:

- Indicator studies (short-term) must not show adverse findings;
- Registrant agrees in advance to additional restrictions on registration should adverse effects be indicated by long-term studies. The additional restrictions would include cancellation if potential risks were judged high enough to warrant such action;
- Pesticide would be limited both in terms of amount allowed in use, as well as restrictions on allowable use sites

Provisional registration would be applied to new chemical registrations and in some instances of registration of a currently registered chemical on a significant new use site.

3. Other Program Implications of Options

The above five options relating to pre-market information requirements have implications for other program areas or aspects of the pesticide program. There are implications for enforcement, monitoring and research as well as risk/benefit decisionmaking. A matrix summary of these aspects of the five alternatives is presented in Figure III-2. The most dramatic differences from reference guidelines, which is nominally the current program, occur with self-certification. This alternative is vastly different from the others in that it places much more burden on the industry to regulate itself. The public-at-large would be responsible for seeking reparation for damages caused by pesticides which could result from use of pesticides with less rigorous testing. More publicly funded monitoring, enforcement and research would be needed for the self-certification approach.

The differences between reference and regulatory requirements are quite nominal in many ways because much of Alternative #2 is now being implemented. EPA announced its intention to implement data requirement regulations several years ago. As a result, although regulatory requirements are not actually in place per #2, the Agency for the most part, is using proposed guidelines to identify requirements to be met by registrants under the current Section 3 regulations of the Act. The industry is generally responding by meeting these requirements.

Implementation of comprehensive data requirements would involve, essentially, implementing the regulatory requirements approach with little or no exemptions. This would significantly reduce the need for risk/benefit decisionmaking and effects research. Rulemaking would need to take place in order to handle waiver policy so as to minimize exemptions, taking due consideration into the Minor Use Amendment of 1978.

Figure III-2
General Characteristics of Alternative Pesticide Regulatory Program Approaches

Characteristics	#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self Certification	#4 Comprehensive Data Requirements	#5 Provisional Registration
1. Key word description	Data requirements result from interaction between OPP and industry.	Formal regulations specifying data required with waivers available.	No pre-marketing data required. Registrants certify to OPP that products do not cause unreasonable risk.	Cook book of data requirements; no waivers; independent of use patterns.	Limited market access given to new chemicals on the basis of acceptable results on short term indicator studies, i.e., mutagenicity studies, structure/activity quantitative analysis.
2. Pre-market testing	Industry safety testing based upon informal industry/OPP interaction and informal use of reference guidelines.	Testing based on regulations. Registrant's, all work from same basis. Waivers are granted with proper justification	Not required but firms likely to test to some degree.	Required on an increased level.	Chronic feeding studies must be initiated but not necessarily completed before provisional registration.
3. Exposure/risk/benefit analysis and decision-making	Moderate levels of effort under RPAR/RS Programs and special problem chems.	Moderate levels of effort for RPAR/RS Programs. Comparative risk assessment work be done on same basis for RPAR analysis.	Higher levels of effort for RPAR/RS programs.	Low levels of effort for RPAR/RS. Maximum data base generated up front.	Rules must be specified which permit the amount of allowable exposure. Exposure controlled by site and production/distribution limitations.
4. Use Management a. Surveys of actual usage b. Ed/trg/certification	Minimum program of labeling, IPM, training. Moderate certification. Minimum data o actual usage.	Minimum program of labeling IPM, training. Moderate certification. Minimum data on actual usage.	Increased importance due to uncertainty of risk factors.	Less important since safety factors may be more well known.	No change from current program.
5. Enforcement	Minimal private app./prog. Moderate commercial applicator and producer enforcement.	Minimal private app./prog. Moderate commercial applicator and producer enforcement.	High private applicator, commercial applicator, and producer enforcement effort.	Could continue as under current program.	Registrant must comply with production/distribution limitations.
6. Effects Monitoring	Minimum program - problem focus.	Minimum program - problem focus.	High priority. Adverse effects need to be identified without prior testing indications. Epidemiology studies for various adverse effects would be needed.	Could continue as under current program.	No change from current program.
7. Effects Research	Minimum OPP Program - being phased down. Moderate ORD effort. Moderate USDA/EPA Exposure work.	Possible reduction in overall effort for EPA; industry would bear burden of being on forefront of testing science.	Greater need for government involvement. Identify problem areas for monitoring program.	Reduction in need for EPA involvement.	Increased need for EPA involvement on potential hazards.
8. Legislative/Rulemaking	Rulemaking only.	Rulemaking only.	Major FIFRA overhaul and rulemaking.	Major rulemaking.	FIFRA amendments plus rulemaking.

Provisional registration is in line with suggestions by the pesticide industry, and others, to limit pre-market testing to a relatively few indicators (or core) studies. After these have been conducted, a chemical could be marketed to some extent while other requirements are being met. This, in effect, now is occurring to a degree with authority to use chemicals under experimental use permits (Section 5) and also for special local needs (Sec. 24(c)).

4. Presidential Task Force on Regulatory Relief

In August of 1981, the Vice President's Task Force on Regulatory Relief identified the pesticide registration program as a regulatory activity potentially needing reform. The Task Force had received comments from business, State and local governments, agriculture, and educational institutions indicating that the registration process appears to unnecessarily delay the distribution of new pesticide products and inhibits new uses of existing products without providing commensurate health and environmental benefits. Comments were received recommending changes in the overall registration process including, Registration Guidelines, the Registration Standards/RPAR process, and Data Call-In. 1/ These comments are briefly summarized in Figure III-3.

Five regulatory options have been proposed for evaluation. The concerns expressed by respondents to the Regulatory Task Force would be impacted differently under the alternative options. One major area of concern raised by pesticide firms in the comments to the Regulatory Task Force is that testing procedures or protocols should not have the force of regulation, but should be made available as guidance only. The Agency proposal, regulatory requirements (#2), adopts this structure whereby testing requirements are issued as regulation, but protocol guidance is made available in non-regulatory documents.

The general criticisms that the current registration process takes too long and is too costly have been addressed in the regulatory impact analysis of alternatives. Steps have been taken to minimize such problems under the current program. Also, they would be very positively affected by adoption of either Alternative #4 (self-certification), or #5 (provisional registration). Self-certification would allow registrants to set their own time frames for registration of products. Generally, operations of OPP would not adversely affect the timeframe for registration of pesticide products. Reduced interaction with OPP would also reduce industry costs to register products. Under provisional registration, data review by OPP would be maintained; however, advance marketing (prior to completion of all chronic testing) of products would alleviate the effects of data costs (relative to the current situation) while, in effect, reducing the pre-market testing requirements.

1/ Comments regarding specific pesticide policy decisions were also submitted to the Task Force. However, only the comments on data requirements and processes will be discussed in this section.

Figure III-3

Summarization of Comments Pertaining to Data Requirements Received by Regulatory Task Force 1/

Concern	Recommendations
Section 3 Registration Process (general):	
Registration process takes too long (as currently conducted) and data requirements impose a financial burden.	°Expedited data reviews °Simplify registration procedures
Registration Guidelines:	
Registration guidelines are too complex and impose expensive testing requirements.	°General outline (as regulation) of "kinds of information" required for regulation °Should not be formal rulemaking, only guidance documents
Registration Standards/RPAR	°Eliminate R.S. process: continue product-by-product approach using 3(c)(2)(B) to fill data gaps °Eliminate or substantially alter the RPAR process
Requirements are rigid and costly reducing available resources to pursue research and in some cases forcing small producers out of business.	°Registrants should jointly develop data and share cost of data production by "market share." Any registrant who agrees to share the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of registration.

1/ Only summarizes comments pertaining to data requirements or related processes.

The registration process is however only one item with which the pesticide industry is concerned. Hence, one cannot conclude industry support for self-certification. In fact, the industry has indicated that self-certification is not a favored option. As will be developed in later sections, industry product liability and the possibility of facing individual state regulations would be of much greater significance without a reasonably strong Federal program

Respondents also suggested substantial revision of, or elimination of, the Guidelines. Self-certification takes this recommendation into consideration. All other options would operate using the guidelines as either formal or informal data requirements. Several respondents also recommended elimination of, or substantial revisions in, the Registration Standards Program, the RPAR process, and Data Call-In. Under options #1, 2, 3, and 5, these programs/processes would not be substantially altered. Under self-certification, option #4, data call-in, would only be used when adverse effects were suspected and the Registration Standard Program (as currently operated) would be eliminated. The RPAR process or a similar process would remain in place in order to evaluate pesticides potentially posing unreasonable adverse effects on the environment.

IV. PESTICIDE PROGRAM IMPACT ANALYSIS

A. Registration Decisionmaking Programs and Their General Pesticide Data Needs

In order to obtain registration for a product, the applicant is required to submit certain information and data in support of the registration application. The types of registration activities which are subject to data or other requirements for registration under FIFRA are shown in Table IV-1. The major data requirements are associated with new chemical registrations and reregistrations which are done largely under the registration standards program.

B. Programmatic Rationale for Various Data Requirements and Associated Guideline Subparts

The registration data requirements and guidelines can be divided by topic area into parts which singly and in combination support program decisionmaking on pesticide products. Each part establishes criteria under which data are needed in support of the registration of manufacturing use and end-use products. Each part also establishes the type of data required when these criteria are met. The preambles to the various guidelines subparts contain complete discussions of the background and issues pertaining to each subpart. The key points as to the scientific rationale, programmatic use of information, consequences of not having the information, and specific alternatives considered have been summarized in the following charts (Figures IV-1 to IV-6).

C. Impacts of Alternatives on Functioning of Pesticide Programs

1. Time to Obtain Registrations

An important aspect of the alternative approaches is their impact on the time required to obtain registrations under FIFRA, particularly for new products. It is in the interest of both the applicants for registration and the Pesticide Program to minimize the time that is necessary to obtain registrations for a product, provided that unreasonable adverse effects are avoided. That new criterion was added for decisionmaking under FIFRA in 1972. By avoiding delays in processing and reviewing of applications, the Agency is being more efficient in its operations and at the same time the pesticide industry and users benefit when products are registered and placed on the market in a timely fashion. This section discusses the potential for impacts on time to obtain registrations from the point of view of the functioning of the pesticide registration process. The significance of the timeliness of decisions from the point of view of the industry is discussed in the industry impacts section of this report.

Table IV-1 Description of Different Registration Actions

Registration Action	Description	Section of FIFRA
New Chemical	New active ingredient	3(c)(5), 3(c)(7)
Amended Registrations	New use, and other label changes	3(c)(5) or 3(c)(7)
"Me Too" Registrations	Identical end use products (same formulations)	3(c)(7)
Supplemental Distribution	Name and address vary but product the same	3
Experimental Use Permit	Interim permit for data collection	5
Special Local Needs	Individual states on a local need basis	24(c)
Emergency Exemption	Emergencies	18
Registration Standard	Standard for registration decisions on an active ingredient	3(g)

Figure IV-1 Data Requirement/Guideline Subpart Program Rationale

	Subpart D; Product Chemistry
PURPOSE:	Identify intentional and unintentional components of products.
SCIENTIFIC RATIONALE:	Toxicity and exposure potential are directly related to components of pesticide products.
CONSEQUENCES OF NOT HAVING INFORMATION:	Unknown major or minor components in pesticides may pose high toxicological risks to humans or environment.
PROGRAMMATIC USE OF INFORMATION:	1. Decisions on allowable inerts; 2. Enforcement of labeled contents; and 3. Tolerance setting.
ALTERNATIVE APPROACHES CONSIDERED:	Identification of components to 0.01% level as opposed to 0.1% level with microbial bioassay screening for toxic components.

Figure V-2 Data Requirement/Guideline Subpart Program Rationale

SUBPART/TITLE:	Subpart E; Hazard Evaluation: Wildlife and Aquatic Organisms Subpart J; Hazard Evaluation: Nontarget Plants Subpart L; Hazard Evaluation: Nontarget Insects
PURPOSE:	Assess the toxicity of pesticides to non-target organisms in the environment.
SCIENTIFIC RATIONALE:	Laboratory and field studies are used to assess the hazards of pesticide use to wild mammals, birds, aquatic life, plants, and pollinator insects.
CONSEQUENCES FOR NOT HAVING INFORMATION:	Pesticide usage without this information may cause population reduction or elimination of species of wildlife and other organisms.
PROGRAMMATIC USE OF INFORMATION:	1. Decisions on acceptable sites, formulations, application methods; 2. Label warnings.
ALTERNATIVE APPROACHES CONSIDERED:	Tiered testing requirements are chosen over uniform testing schemes.

Figure IV-3 Data Requirement/Guideline Subpart Program Rationale

	Subpart F; Hazard Evaluation: Humans and Domestic Animals
PURPOSE:	Assess the acute and chronic affects of human and domestic animal exposure to pesticides.
SCIENTIFIC RATIONALE:	Laboratory animals serve as indicators of potential response of humans and domestic animals upon exposure to pesticides.
CONSEQUENCES OF NOT HAVING INFORMATION:	Determination of acceptable levels of exposure not possible. Health effects in population with unknown causes might occur.
PROGRAMMATIC USE OF INFORMATION:	1. Decisions on acceptable sites, formulations, application methods; 2. Label warnings; and 3. Tolerance setting.
ALTERNATIVE APPROACHES CONSIDERED:	Various combinations of short-term and long-term studies have been considered. Use of indicator studies for chronic effects is not scientifically supported currently.

Figure IV-4 Data Requirement/Guideline Subpart Program Rationale

SUBPART/TITLE:	Subpart G; Product Performances: Public Health Uses
PURPOSE:	Ensure that pesticide products control public health threatening pests listed on labels.
SCIENTIFIC RATIONALE:	Ineffective pesticides cause undue pollution without offsetting benefits of pest control. Public health pests, if not controlled, adversely affect human health.
CONSEQUENCES OF NOT HAVING INFORMATION:	Public health will be seriously affected. Increase in unnecesary pollution. Increase in consumer fraud.
PROGRAMMATIC USE OF INFORMATION:	1. Decisions on acceptable sites, pests controlled, allowable label claims; 2. Label warnings; and
ALTERNATIVE APPROACHES CONSIDERATIONS:	Extend product performance guidelines to non-public health uses was considered; decision has been made that markets will effectively keep ineffective products off of market for those other uses.

Figure IV-5 Data Requirement/Guideline Subpart Program Rationale

SUBPART/TITLE:	Subpart K; Exposure Data Requirements: Reentry Protection
PURPOSE:	Provides data on residues and residue dissipation of pesticides on foliar and other surfaces. Data used to establish reentry intervals for agricultural workers.
SCIENTIFIC RATIONALE:	Workers may be exposed to pesticide residues on crops and surrounding area. Residue levels vary with crop, pesticide formulation, meterological condition, etc.
CONSEQUENCES OF NOT HAVING INFORMATION:	Workers subjected to unknown hazards from pesticide exposure.
PROGRAMMATIC USE OF INFORMATION:	1. Establish reentry intervals; 2. Label warnings
ALTERNATIVE APPROACHES CONSIDERED:	Establish reentry residue levels as opposed to reentry time intervals. Cover all crop sites as opposed use patterns with high exposure potential.

Figure IV-6 Requirement/Guideline Subpart Program Rational

SUBPART/TITLE:	Subpart N; Environmental Fate
PURPOSE:	Describes data needed on pesticide metabolism, degradation, dissipation, mobility, and accumulation in the environment for purposes of exposure assessment.
SCIENTIFIC RATIONALE:	Pesticide chemicals may be chemically changed and physically moved from intended site after application. Sunlight, water, soil, and air all may interact with pesticides.
CONSEQUENCES OF NOT HAVING INFORMATION:	The fate and persistance of pesticide residues in the environment could not be determined.
PROGRAMMATIC USE OF INFORMATION:	1. Decisions on acceptable sites, formulations, application methods; 2. Label warnings; 3. Tolerance setting.
ALTERNATIVE APPROACHES CONSIDERED:	Several options on choices between laboratory studies and field studies were considered and choices made.

a.) Elapsed Time to Obtain Registrations [1]

Approximately 7 years of elapsed time occur between the time a new chemical entity is discovered and the time it can be marketed with a full commercial registration under FIFRA, as amended, in the 1970's. Between 1973 and 1980, an average of 88 months (7.3 years) elapsed between discovery of chemicals and the receipt of registrations (Table IV-2). During the period since the 1972 amendments, there has been no consistent trend up or down in elapsed time from original discovery (Figure IV-7). The peak of 110 months was reached in 1977 at the height of the difficulties in the registration process precipitated by a number of lawsuits concerning compensation for proprietary data. This problem is still a complicating factor in the program, but has been ameloriated to a degree by 1978 amendments and rulemaking by the Agency concerning data compensation.

b.) Processing Times of Applications in EPA

Processing of registration applications for new active ingredients (FY 82) is targeted to take an average of 28 weeks for new chemicals and an average of 22 weeks for new bio-rationals. Processing time varies however, depending on the complexity and quality of test data submitted for scientific review. This is demonstrated from an historic perspective in step 3 of Table IV-3. Few new pesticide chemicals, with or without a tolerance petition, attain registration within a single cycle of the EPA procedure.

Alternative #4 (comprehensive data requirements) would represent the most stringent registration procedure of a new pesticide chemical. This option could conceivably lengthen the maximum time required for the existing procedure, especially if any data gaps were revealed during the Hazard Evaluation Division review.

Alternative #3 (self-certification) would require the least amount of EPA involvement in the registration of a new pesticide chemical. Review of test data would be eliminated as it would not be required for registration. Time required would be greatly shortened in this instance since registrants would self certify that no unreasonable risk would result from product use.

Reference guidelines (#1) best represents the current EPA procedure for new pesticide chemical registration. The primary concern at this time is in regard to the completeness of submitted risk data, which determines the number of times the concurrent scientific review period must be repeated. The risk data review is the most time consuming step of the registration process. It should be noted however, that the review status of every new pesticide chemical is checked on day 150 of this period and the findings are reported to the applicant.

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[1] The data on elapsed time to registration presented in this section are those published by the National Agricultural Chemical Association, based on its annual surveys of participating members.

Table IV-2. Elapsed Time to Obtain Registrations for New Active Ingredient Under FIFRA, Available Years, 1963-80

	Average elapsed time to full commercial registration from:		
Year	Final submission for registration	First temp/ experimental submission	Discovery of chemical
	Months		
Prior to 1963	NA	6	61
1963-67 average	NA	7	61
1967-71 average	NA	18	69
1970	NA	11	63
1973	NA	22	80
1974	18	42	97
1975	14	30	93
1976	15	38	74
1977	29	40	110
1978	14	32	69
1979	19	44	92
1980 a/	23	35	88
1973-80 average	19	35	88

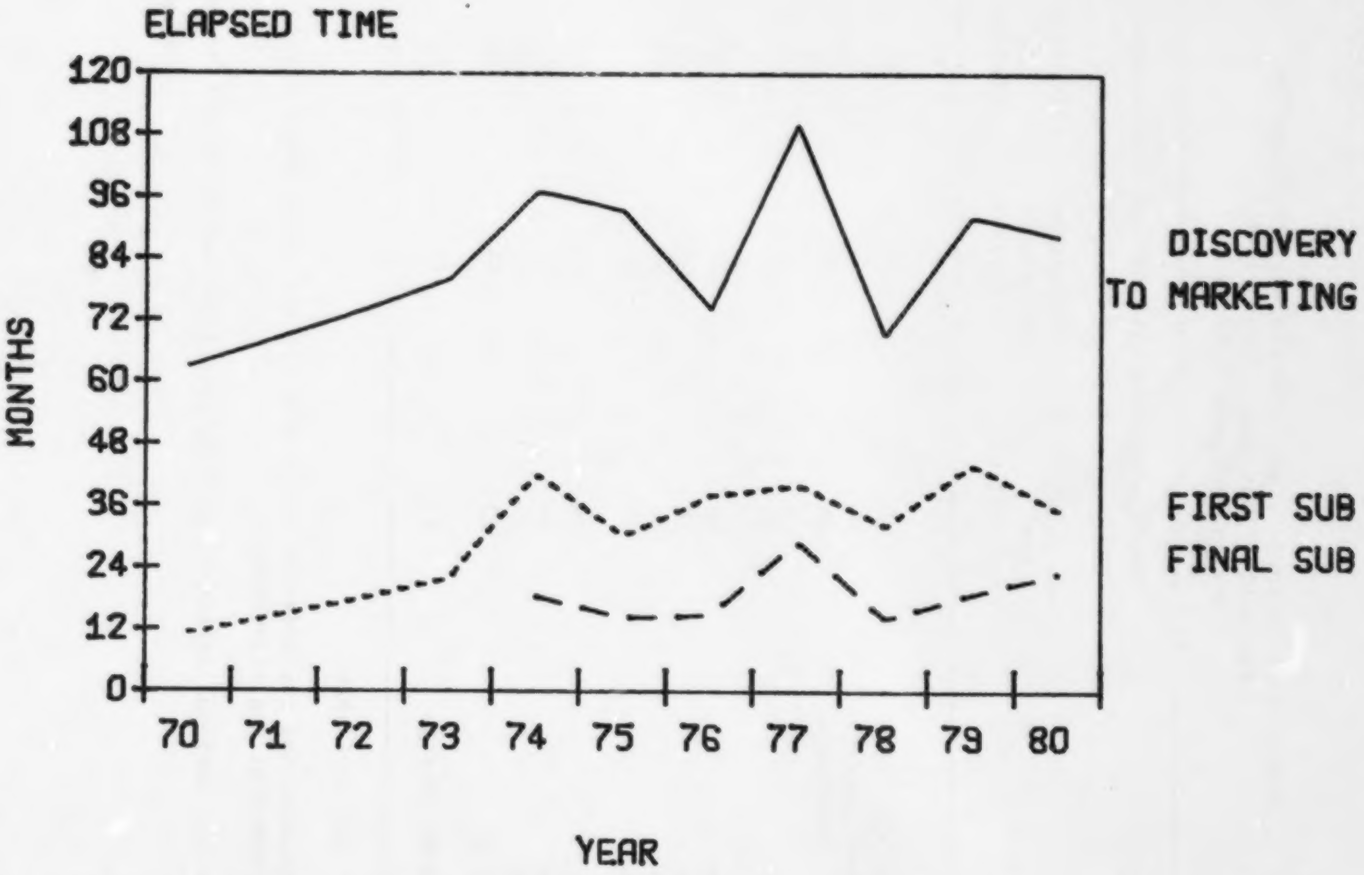
NA - Not available.

a/ Conditional registration only; data for all other years are for full comercial registrations.

Source: National Agricultural Chemicals Association, Annual Surveys.

FIGURE IV-7

ESTIMATE OF TIME REQUIRED TO COMMERCIALIZE
A PESTICIDE PRODUCT, 1970-1981.



SOURCE: NATIONAL AGRICULTURAL CHEMICALS ASSN., INDUSTRY PROFILE SURVEYS
NOTE: DATA FOR 1980 ARE FOR CONDITIONAL REGISTRATION

Table IV-3. Time Requirements for EPA Administrative Regulatory Procedure for New Pesticide Chemical, FY 81 and FY 82

Action	Time Requirement FY 81 & FY 82 weeks
1. Administrative Classification of Pesticide Chemical	2
2. Acknowledge Receipt of Registration Application	1
3. Hazard Evaluation Division Data Review	24-32
4. Receipt of Data Review by Registration Division and Industry Notification	1-2
5. Industry Response to EPA Notice of Data Review	4
6. Supplemental Data Generation if Required	4-52
7. Repeat Step 3 (conditional registration)	16-24
8. Label Review, Provisional EPA Acceptance	2-4
9. Industry Conformance to Administratiave Details	2-4
10. EPA Formal Acceptance of Pesticide Chemical Registration	2-4
Total for Full Registration	58-129
Total for Conditional Registration (Omit Steps 6 and 7)	38-53
Total Time Savings	20-76

Provisional registration (#5) is a somewhat less rigid registration method than the existing conditional registration process which is described in Section 3 of FIFRA. This option, like conditional registration, could effectively shorten the scientific review period, by not requiring some of the lengthier toxicological tests to be completed at the time of application for registration.

Finally, regulatory requirements (#2) would also have a shortening effect on the present registration process. By formulating specific data requirements and granting test data waivers, time could be reduced. The applicant could further benefit by being relieved of performing risk-related tests which may not apply to the pesticide chemical in question.

Ostensibly, all of the pesticide chemical registration options presented deal primarily with some manipulation of the quantity and totality of pre-market test data. With the concurrent scientific review period requiring the majority of time in the registration procedure, modification of the requirements and timeliness of this step would produce the greatest benefit for the individual applicant.

In addition to reducing EPA review time, elapsed time to reach registration determinations could be reduced by the time necessary to conduct certain tests, particularly the human hazard chronic tests. This is especially true for the industry self-certification option and provisional registration. Savings for those options would be in the range of 2-3 years compared to guidelines. The estimates of time savings cannot be made precisely because of differing modes of operations of firms and multiple use of test facilities and projects (to meet various needs within the firm and for other possible regulatory requirements).

Taking into account the time it takes the Agency to process applications and the time it takes for various testing/data collection activities to take place by registration applicants, the alternative approaches would be likely to have the following approximate times required from original discovery to obtain registration of a new chemical:

Alternative	Months
#1	85-95
#2	80-90
#3	60-80
#4	100-120
#5	60-80 1/

Options #3 and #5 offer the greatest opportunities for time saving.

1/ Refers to initial limited marketing only.

2. Certainty of Registerability of Pesticides

An optimum pesticide registration decisionmaking program, from the point of view of information input to those decisions, would be one in which the cost of additional information would be at least equal to the benefits of additional information (i.e., cost of further information would outweigh the benefits). The costs in this instance would be in terms of user benefits denied, costs of generating the additional information to the industry, dissipated market advantage and other time-related costs to the industry. The benefit, on the other hand, is the value of the reduction in the number of incorrect registration decisions made. The purpose of this section is to briefly discuss the accuracy of decisions that would be likely to result under the 5 program options.

The most accurate alternative would be #4, comprehensive data requirements, in which a full complement of data would be obtained before authorizing any registration of a new active ingredient. Under that approach, the maximum amount of information would be obtained, thus minimizing the chances of a chemical with unsatisfactory risk properties being registered.

Options #1 and #2 would rank second in accuracy of decisions with option #2 being somewhat better than option #1. Generally, somewhat more strict requirements would be met under option #2 than option #1, thus improving the accuracy of decisions to some degree. Option #5, provisional registration, would rank next. There would be a tendency for more incorrect decisions to occur with that approach due to the more limited information available at the time usage was authorized. On the other hand, usage would tend to be limited to the less risky sites until all testing deemed necessary would in fact be completed.

The poorest alternative, in terms of accuracy of decisions by the Federal Government, would most likely be the self-certification option. Here, the regulatory body would have quite limited information to base its decision upon, and the industry would basically be relying on its own judgement as to the pesticide's safety. Quality control could be a particular problem as some firms are likely to be much more rigorous and conscientious in their testing and decisionmaking than are other firms.

The cost of reviewing registration applications can be impacted by the guidelines and alternatives. Where guidance is available to the registrant as in options #1, #2, and #4 and #5, the registrant is in a better position to determine what is actually needed to obtain a final registration. This can permit building of efficiences into the research and development activities of the firms and also minimizes the number of times applications need to be resubmitted to the Agency before they are successful in getting registrations. During FY 1977, the average number of submissions was 3.4 per application granted (more recent data are not available).

At this point, it is very likely that provisional registration (and possibly self-certification) would result in significant numbers of resubmissions because of the uncertainty in submission requirements.

Producers of pesticides would tend to benefit from options #1, #2, and #4 because fewer R&D resources would be wasted on "loser" chemicals. Fewer resources would be misspent on the development of products sought to be registerable but upon further, closer, preregistration testing would be screened out. This would eliminate "dead weight" burden of R&D expense undertaken with no ultimate producer/user benefit in the form of a new registered chemical at the end.1/

Alternatives which induce the industry to do more "up front" safety testing of chemicals, benefit not only the public at large due to reduced potential exposure and risk at a later time, but help the industry in identifying "losers" at the earliest possible date. Alternatives which let the research and development process continue on, substantially longer, before critical risk information is available tend to drive costs of the industry upward in the long run. Options #3 and #5 allow this phenomenon which could add to R&D costs, as well as other costs in the case of either discovered losers or chemicals which ultimately must be removed from the market.

3. Interrelationships with Other Statutes/Programs

In regulating the use of pesticides under FIFRA, the Office of Pesticide Programs interacts with and/or affects other Federal and regulatory programs. Chronic and acute toxicity test data and degradation information collected under environmental fate data requirements are useful to OSHA in their regulatory activities and are also used in decisions made under Resource Conservation and Recovery Act (RCRA). Furthermore, the data are used to establish tolerances for pesticide residues in foodstuffs under FFDCA; these tolerances are established by EPA and enforced by FDA. The level of Federal data collection and evaluation of the detrimental effects of pesticides also determines State decisions pertaining to the need for supplemental State and local regulation (above those regulations imposed by Federal government) of pesticide use. As alternative regulatory approaches are evaluated, the impacts of these approaches on other Federal and State decisionmaking activities must be recognized.

Under regulatory option #3, self-certification, pre-market testing of products would not be required by the Office of Pesticide Programs. The extent of testing performed would be at the option of the registrant. The absence of data collection on the various detrimental

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1/ There is no pesticide program benefit from this type of action (in terms of reduced actual health or environmental impacts) because the products never reach market. When they do so, and it could have been prevented by other options, there would be such program benefits.

effects caused by pesticides could hamper regulatory activities under OSHA, FFDCA, and RCRA. Theoretically, chronic and acute toxicity test data for new chemicals would only be available at the registrants' discretion under a regulatory policy of self-certification.

Regulatory activities under FFDCA would be most severely affected. Currently, tolerance setting requires a full battery of test data and description of analytical chemical methodology for detecting and measuring residues. In the absence of access to such data, tolerances could not be set by OPP under a self-certification regulatory approach. Alternative mechanisms for tolerance setting would have to be established. Clearly abandonment of tolerance establishment and enforcement could severely endanger the health of U.S. consumers.

The lenient Federal regulatory stance under a registration program of self-certification may be considered unacceptable by many of the State governments. Currently, California, Wisconsin, New York and other states often impose more stringent regulations than EPA. Data collection and evaluation at the State level could considerably increase the aggregate costs of pesticide use and production. States would have to substantially increase their staffs and/or create entirely new program areas. Industry currently believes that regulations under FIFRA allow the States too much discretionary power to require data and regulate beyond the standards established by the Federal government. This is evidenced by industry testimony presented to the House Agriculture Committee during hearings on FIFRA authorization during the spring and summer of 1982.

The Office of Pesticide Programs, in administering FIFRA, is primarily concerned with preventing unreasonable adverse effects from pesticides. This goal cannot be expected to be always consistent with industry goal of maximizing the certainty of the registerability of products. An effective regulatory program can attempt to maximize the certainty of registerability given the constraints of the requirements of FIFRA.

4. Impact of Alternative Regulatory Options on Pesticide Program Costs

a.) EPA Programs

In the President's budget prepared in March 1981, the estimated pesticide budget in FY 1981 was $69.6 million. The estimated budget for FY 1982 is $62.1 million. The FY 82 reduction in the budget occurs mostly in the areas of Research and Development and Registration Standards Programs.

An analysis of the impact of alternative regulatory options on the pesticide budget for a typical year is contained in Table IV-4. It shows that the largest resource saving to EPA occurs with regulatory requirements (option #2). The cost savings is estimated to be slightly over $4 million for a typical year which is about 6% of the FY 1982

Table IV-4

Impact of Regulatory Alternatives on Pesticide Program Budgets,
Typical Current (FY 82) Year Basis

Program	Current Budget Estimate (1982)	Regulatory Alternative				
		#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self. Cert.	#4 Comp. Data	#5 Provisional Registration
	- - - - - - - - - - - - - - - - - - Millions - - - - - - - - - - - - - - - - - -					
Research & Development	6.9	NC	-0.4	2.0	-0.7	0.7
Registration	7.9	NC	-0.4	-4.0	4.0	-0.2
Special Reg.	2.0	NC	0.4	-0.4	0.8	-0.2
Tolerances	2.2	NC	NC	-1.1	NC	NC
Registration Standards	10.5	NC	-0.5	-6.0	3.0	NC
RPAR Reviews	16.0	NC	-3.2	4.0	-6.0	1.0
EIS Preparation	0.1	NC	NC	NC	NC	NC
Pesticide Enforcement	4.3	NC	NC	1.0	NC	1.1
Grants Support	0.4	NC	NC	NC	NC	NC
Grants	8.7	NC	NC	1.0	-1.0	1.0
Certifications & Training	2.5	NC	NC	1.2	NC	NC
Federal & State Programs	0.5	NC	NC	2.0	NC	NC
Total	62.0	NC	-4.1	-0.3	0.1	3.4

NC = No change
- = decrease

Source: EPA budget material and EPA estimates of changes under the Regulatory Alternatives.

budget. Reference guidelines, self-certification and comprehensive data requirements (options #1, #3 and #4) do not significantly change overall budget requirements. Provisional registration would result in an increased cost of $3.4 million (about 5%).

b.) USDA/SAES Programs

Program costs for USDA/SAES (State Agricultural Experiment Stations) relating to pest control, totaled $336 million in FY 79 (3,104 scientist years).

Presented in Table IV-5 is a qualitative analysis of impacts of the five options. The analysis indicates relatively minor impacts, based on a brief review. Options #2, #4 and #5 would result in fewer RPAR's and hearings which could save the USDA and the states up to $10 million per year. Option #3 would increase needs for applicator training and also RPAR's/hearings to a degree.

D. Impacts on Acute Human Hazards

1. Nature and Extent of Acute Human Hazards of Pesticides

a.) Acute Toxicity of Pesticides

Pesticides are biologically active chemicals that are intentionally selected and introduced into the environment for the express purpose of killing or injuring some undesirable form of life. Unfortunately, these chemicals as a rule, also have the inherent capacity to kill or injure desirable life forms, including man. This general lack of target specificity is due, in part, to pesticides' abilities to alter life processes shared by many organisms. Assurance of safety to desirable non-target species greatly depends upon the judicious selection of pesticides, quantities and methods of use that minimize potential risks to these species. Assessment of this risk to humans requires an accurate knowledge of the inherent toxicity and an estimation of the likelihood and magnitude of exposure to them.

The known effects of pesticides range from barely detectable to discomfort to gross morbidity and mortality. Depending on the intensity and duration of these effects, they are broadly characterized as acute or chronic in nature — acute effects being relatively more severe and/or shorter duration, whereas chronic effects are those that persist over a long period of time. Acute toxicities most often, though not necessarily, occur following one or a few exposures to relatively high levels of pesticides, such as might occur with persons who handle, use or otherwise come into direct contact with them. By far, the vast majority of reported poisonings are the result of occupational exposures, careless use, misuse or mishandling acutely toxic pesticides.

Table IV-5

Resources Allocated to Research on Pest Control by Federal and State Governments, (Pesticide Regulatory, Research and Educational Program Costs), FY 1979/80

	Reference Guidelines (Current Program) #1		Regulatory Requirements #2	Self Certification #3	Comp. Data #4	Provisional Registration #5
	$ million	Scientist Years				
FY 79	336.5	3,104	Slight increase ($5-10 million due to fewer RPAR's)	Some increases in State Ed. Programs, more RPAR's and hearings ($10 to $20 million)	$10 million decrease due to fewer RPAR's and hearings	Slight decrease ($5-10 million due to fewer RPAR's)
FY 80	375.5*					

*ARS data are available for FY-80 actual gross appropriations. FY-80 funding increased 11.6 percent from FY-79.

b.) Acute Exposure

Acute exposure to pesticdes may occur under many circumstances and by several routes. The most important of these are exposure from handling of concentrated pesticides during mixing, loading and cleanup activities, exposure from entry into treated areas following application, incidential exposure to bystanders near sites being treated, and dietary exposure from consumption of foods containing pesticide residues. Exposure from all of these routes is somewhat documented in the open scientific literature and cited in OPP regulatory documents such as RPAR Decision Documents.

c.) Effects

In the United States, approximately 140 fatalities (0.65 per million population) due to pesticide poisonings are reported in a typical year. It has furthermore been estimated that about 100 nonfatal poisonings occur for each fatal one (Hayes, 1975).

2. Impacts of Alternatives on Exposure and Risk

Testing designed to identify and quantify the acute effects of pesticides ordinarily consists of a set of 4 or 5 short-term relatively inexpensive studies which are universally accepted as being essential for the evaluation of short-term or acute hazards. There is little doubt that industry requires such studies to be performed on nearly all pesticide products, and that they would generally be performed and reported in a satisfactory manner, even without a regulatory requirement to do so. Therefore, selection of a specific overall approach by EPA to regulate pesticides or finalize the guidelines generally would have little impact on the evaluation of acute risk. There is some possibility that risk could increase to a degree under self-certification.

Pimental, et al. (1980) has calculated the economic costs of accidental pesticide poisonings. The costs have been updated to 1980 values. Also a discount rate of 10 percent has been used in computing the present value cost of fatalities. The cost of each acute poisoning is estimated to range from $39 for physican services to $112,327 in the case of death. The total direct and indirect costs of acute poisonings is estimated to be $15.2 million annually. It should be noted that the estimates represent economic costs and should not be interpreted as value of life estimates.

The alternative approaches to achieving regulatory objectives on information requirements have previously been characterized as having no significant effect on the generation of data about the acute effects of pesticides. The conclusion is based on the presumption that the basic acute toxicity studies are relatively low cost and that knowledge of acute toxicities is needed as basic information for the market development of a pesticide. The pesticide industry is thus expected to perform studies to measure the acute toxicity of their products regardless of the regulatory environment under which they must function. Therefore, changes in the acute effects testing and associated costs would be minor under any of the alternative approaches analyzed in this study.

E. Impacts on Chronic Human Hazard

This section will discuss in general terms 1) the exposure to and chronic toxicity of pesticides as currently used; 2) project the type of changes which can be expected under alternative regulatory scenarios; and 3) project as fully as possible the cost of adverse chronic health effects under each regulatory scenario.

1. Nature and Extent of Chronic Human Hazards of Pesticides

a.) Chronic Toxicity of Pesticides

Chronic effects are those that tend to develop over a relatively long period of time. Some of these effects such as hypersensitivities, allergies, storage of chemicals in body tissues and adaptive liver changes may be regarded as being of lesser concern in humans. But also included in this category are effects that are considered to be very severe and serious such as effects on the nervous system, birth defects, inheritable changes in genes and cancers. These latter types of effects are recognized as being seriously debilitating and are often of an irreversible nature. In addition, considerable experience from animal studies clearly suggests that chronic effects are potentially capable of affecting nearly every organ and system in the human body.

b.) Chronic Exposure

Exposure to pesticides may occur under many circumstances and by several routes. The most important of these are exposure from handling of concentrated pesticides during mixing, loading and cleanup activities, exposure to diluted spray during application, exposure from entry into treated areas following application, incidental exposure to bystanders near sites being treated, and dietary exposure from consumption of foods containing pesticide residues. Exposure from all of these routes is now reasonably well documented in the open scientific literature and cited in OPP regulatory documents such as RPAR Decision Documents.

(i) Dietary Exposure

Since 1964 the Food and Drug Aministration and the U.S. Dept. of Agriculture have monitored the pesticide residues in the American diet. This surveillance program is referred to as the Total Diet Program or the "Market Basket Survey." In this program the food in the "Market Basket" is usually defined as the food constituting the diet of the average American male, age 15 to 20 (the nation's biggest eater). In a related program, parallel data are collected for infants and toddlers.

Pesticide residues in the American diet are at a level considered acceptable by EPA and generally much less than the acceptable daily intake (ADI) recommended by the Joint Committee on Food Additives of the United Nation's Food and Agricultural Organization and the World Health Organization (FAO/WHO).

(ii) Population Exposed

Table IV-6 presents estimates of the number of individuals in various groups which are chronically exposed to pesticides. The final figures presented in this table are not additive in that a single individual could fall into more than one of the population categories.

2. Costs of Chronic Effects, as Impacted by Alternatives

The purpose of this section of the analysis is to present estimates of the unit cost of chronic effects and relate these to the changes which can be expected under the five regulatory options under consideration.

The last part of this section will discuss each option in turn; the first will not, since the information presented applies equally to all the options.

a.) Unit Costs of Chronic Effects

It was possible to estimate the unit costs of cancer using published data from the health care sector of the economy. Data relevant to unit costs of other chronic effects which could be linked to a pesticidal cause were not available. In Section IX, some hypothetical unit costs for other effects have been postulated and their implications explored.

Cancer, being one of the primary chronic effects, appears to be the largest contributor to the cost of pesticide-related health effects. Table IV-7 presents the derivation of the estimate of the unit cost of cancer (average per case cost). The derivation depends, in large part, on data and estimates on aggregate costs of chronic effects (see detailed cost/benefit analysis report). It is estimated that the average cost of cancer is $52,000 including both direct and indirect costs. Direct costs consist of medical care costs and indirect costs are the discounted value of lost wages due to morbidity and mortality.

It is recognized that the "human capital" approach, upon which the above estimate is based, is not an ideal method for estimating the full cost of a mortality to society. Such estimates do not include for example the cost of pain and suffering, and as such are not estimates of the value of lifesaving.

Table IV-6

Estimated Number of Persons Chronically Exposed to Pesticides by Type of Exposure

Population Category	Number of Persons (1000)	Type of Exposure
Total U.S. Population	220,099 a/	Dietary
U.S. Farm	6,241 a/	Occupational
Private Certified Applicators c/	1,097 b/	Occupational
Commercial Certified Applicators	114 b/	Occupational

a/ Source: USDA. 1980. Agricultural Statistics. Washington, D.C.

b/ Source: American Association of Retired Persons. 1981. Collection of State Data on Certified Applicators and Structural Pest Control Program. Washington, D.C. July.

c/ A large percentage of this category would also be included in the U.S. farm population figures.

Table IV-7

Estimated Cost of Cancer

Total Number of Cancer Cases a/	660,680
Total Direct and Indirect Cost of Cancer (1980) b/	$34,349,000,000
Unit Cost of Cancer	$52,000

a/ Hartunian, N.S., et al., 1980. The Incidence and Economic Cost of Cancer, Motor Vehicle Injuries, Coronary Heart Disease, and Stroke: A Comparative Analysis. American Journal of Public Health. Vol. 70, No. 12. December.

b/ Estimated from U.S. Dept. of HEW. 1978. Health-United States. Public Health Service. Washington, D.C. December.

b.) Impacts of Guidelines and Alternatives

Since it is not really possible to quantitatively estimate the changes in chronic health effects across the regulatory options being considered, this section will discuss the health cost impact of chronic effects in largely qualitative terms (see Table IX-4).

(i) Reference Guidelines

This option would essentially continue the status quo and as such would not involve a change in the health cost currently being incurred. Consequently, the health costs resulting from pesticide use are projected to remain at the current levels.

(ii) Regulatory Requirements

Health costs should be reduced slightly under this option. Because of test protocol specification, information on potential chronic health effects are likely to be more detailed than the information currently being prepared by registrants. In practice, however, it is likely that this option would not generally result in significantly different health costs than the reference guidelines.

(iii) Self Certification

It is anticipated that this option would lead to a significant increase costs due to adverse health effects. Basic economic incentives militate against doing high quality chronic effects testing. Once in place, it would take a considerable time for chronic health problems to become apparent under this option. Because of long latency periods, the full extent of the resultant health cost increase may not be known for years.

(iv) Comprehensive Data Requirements

Chronic health effects costs under this option would be very similar to those under Option (ii). However, some reductions in the level of chronic health risks can be expected to result from the shear volume of testing which would reduce the probability of accepting false negative results from any single test.

(v) Provisional Registration

This option would introduce considerable uncertainty as to what adverse chronic effects could be expected from a pesticide. There is considerable disagreement in the scientific community as to how reliable indicator studies are. This would drive health costs above the level expected under the reference guidelines. At best, health costs would be no lower than those resulting from that option.

F. Impacts on Environmental Hazards

1. Introduction

Currently 1.2 billion pounds (a.i.) of pesticides are being applied to 230 million acres annually. This represents almost 11 percent of the U.S. land base. Given the periodic nature of pest infestations and the multi-year rotations of timber stands, the percentage of the land base treated with pesticides over a longer period of time (say ten years) is much higher. With the use of pesticides on this extensive a scale, the potential for environmental damage is immense. David Pimentel and his colleagues have estimated that non-target environmental effects of pesticides cost the United States some $515 million annually (D. Pimentel and J. H. Perkins eds., Pest Control: Cultural and Environmental Aspects, Westview Press, Boulder, Colo., 1980, p. 136). This estimate excludes recreational and existence values of the damaged environment. Hence, there is a need to carefully screen each new pesticide prior to registration for potential adverse environmental effects.

2. Toxic Effects

The response to a pesticide can be as varied as the number of species exposed to it. The extremes of the response range from no response to death. Death may involve only a few individual organisms, whole age cohorts, or even whole populations of specie. Even though immediate toxic effects rarely affect an entire population, significant population loss can have a major effect on specie reproduction and consequently its associated ecosystem. The magnitude of this effect can vary from small to large. Usually it will be small, however it will nonetheless exist. The ideal situation is for non-target organisms not to be affected at all. This is rarely the case; in any biological situation, things are rarely "black and white". Besides immediate toxic effects, sub-lethal or chronic effects are possible.

3. Chronic Effects

There are many manifestations of chronic pesticide exposure. Some pesticides have the ability to disable the complex reproduction cycle without causing death to the individual exposed. The reproduction cycle is very complex in all organisms, from the simplest plants to man. If any step is altered, changed or blocked in any way, the result can be reproduction failure. A well known example of a reproduction cycle alteration resulting in a large population decline, is DDT's thinning effect on eggshells.

Other chronic problems not related to reproduction, are behavioral changes. An example is the effect organophosphate insecticides (OPs) have on birds and mammals. OPs inhibit an enzyme crucial to the proper functioning of the nervous system. When the enzyme inhibitor is present, birds and mammals become lethargic.

A third classification of chronic problems facing non-target organisms, is habitat destruction or alteration. Admittedly, in most cases this problem is generally confined to less mobile organisms, but it too can be a problem to larger more mobile organisms as well.

4. Population Dynamics

Although this is not the forum for a complete discussion of pesticidal effects and population dynamics, a brief explanation is needed to complete the discussion of the benefits of the testing requirements. The removal of an individual from a population, for whatever reason, has an effect on that population. Pesticides have the ability to exert localized as well as widespread effects. Population dynamics deals with a multitude of interwoven factors relating to one another. Some of the more important factors are food abundance, predator pressure, available habitat and reproduction potential. It has been demonstrated that pesticides do have an effect on all of these; thus pesticides have the potential to significantly effect non-target populations. Can the effect of a pesticide on a population be predicted prior to the pesticides release? Yes, but the amount of information normally available is insufficient to make quantitative predictions. The type of effect that can be anticipated, is generally all that can be predicted.

5. Environmental Fate

Environmental fate information is essential to anticipate these hazards. It is extremely important to know the potential amount of a pesticide in a certain matrix of the environment, how long it will persist there, its potential for biconcentration in the biota of that matrix, for movement to other matrices of the environment, and by what mechanisms and to what substances it will degrade. This information is obtained from the studies delineated in the environmental fate guidelines.

It is anticipated that the types of adverse environmental effects described above can hopefully be predicted and avoided in the future by a careful analysis of the environmental fate parameters generated from the required scientific studies.

6. Impact Alternatives

What are the alternatives and how do they effect the quality of a hazard assessment?

a.) Reference Guidelines

The current program has been established to require more studies necessary to determine hazards to humans, livestock, wildlife and plants. The tests requested provide the information needed to identify the ecological risks associated with a chemical use.

The past record speaks quite well for the system. Few, if any, chemicals registered after 1978, when this program went into operation, have been cancelled or suspended. This is not so for chemicals registered prior to that time.

b.) Regulatory Guidelines

It is impossible to predict and establish a complete testing program prior to the existance of a chemical. There are as many different problems with a chemical as there are organisms exposed to it. Thus, a sequential tiered-testing strategy for identifying ecological effects was developed, and is currently being used by OPP. The proposed regulatory guidelines for ecological testing merely codifies this and specifies the best current practices with regard to the protocals for the tests used in each tier.

c.) Self-Certification

Theoretically, self-certification is a good option. The chemical companies know their chemical better than anyone else. During the product development phase, the firm will examine many of its properties. They examine the chemical's toxicity to many organisms in the attempt to identify a marketable product. The only problem with this system are conflicts between the cost of testing, the amount of profit to be made, and the speed with which their competition is moving. If these obstacles could be overcome and an adequate amount of motivation instilled, the system might work. Whereas, fear of liability suits would no doubt provide motivation for human hazard testing, such a concern is not likely to be present with regard to most ecological hazards and hence provide no motivation for this type of testing.

d.) Comprehensive Data Requirements

Simply stated, this would require all tests for all chemicals. These subparts have a tier system built into their requirements. The higher-tier tests tend to be long-term field studies that are quite expensive. Unless the lower-tier tests indicate a potential problem, information from higher-tier tests are redundant. Thus, this option is much less cost-effective than regulatory guidelines.

e.) Provisional Registration

Initial testing sufficient to insure a pesticide's safety, even in limited use, would have to be equivalent to the first tier of ecological testing, as proposed in the guidelines. If monitoring of the pesticide in its limited use is to effectively identify chronic-type or longer-term fate problems, such monitoring will have to be so structured as to be virtually indistinquishable from the higher tier tests being proposed. Thus, in terms of testing costs, there is probably not much difference between the regulatory requirements being proposed and the provisional registration alternative. The larger the provisional use allowed, the greater the risk of environmental damage; however, unless such use is relatively large, little income will be generated to offset testing costs.

7. The Value of Environmental Benefits Emanating from the Alternatives

a.) Introduction

The benefits to be gained from the alternative methods for assessing environmental risk from pesticide use depends first on the number, specie, and location of the plants and animals likely to be protected under each method as opposed to another, and secondly, on the value society places on these plants and animals in particular settings. The types of plants and animals, let alone their number that would be ultimately protected from harm by the regulatory guidelines being proposed, in particular Subparts E, F, J, L and N, as opposed to each alternative, cannot be predicted. However, social values have been estimated for certain species of wildlife and aspects of the natural environment. In addition, values can be developed for non-target species that have commerical value. A number of these estimated values are presented and discussed below to serve as indicators of the importance that should be placed on preventing ecological damage from pesticides.

b.) Types of Benefits

Wildlife, plants and particular natural ecosystems have value to individuals, and hence society, in terms of their use or potential use, but also in terms of their very existence. Use value is a reasonably straightforward concept. Use can either take the form of commercial harvesting of certain species or a recreational activity for which the specie or particular ecosystem is essential. Value is more or less directly measured by observing what people are willing to pay for the harvested wildlife or expend in pursuit of the recreational activity.

The option value is the amount individuals would be willing to pay to preserve the resource (in a usable state), until future conditions are known with sufficient certainty to establish its subsequent use values.

Existence value relates to the satisfaction individuals obtain vicariously from the knowledge that species or ecological complexes survive, even though they may have no interest, or prospect, of being exposed to them directly. Existence value is the amount they would be willing to pay to insure such survival.

Bequest value is in many respects similar to existence value. It is the value individuals place on the satisfaction they derive from endowing future generations with an undiminished natural environment.

c.) Commercial Use Values

Salmonoid species tend to be more sensitive to the toxic effects of pesticides than other finned fishes. The U.S. Forest Service estimated (Table 1, "Revision of the 1980 RPA Values", October 23, 1979) that the dock-side value of anadromous (salmon and steelhead) fish was $630-$800 per thousand pounds. Retail value would be much higher. Clearly pesticide intrusion into the rivers where salmon and steelhead spawn can have major economic consequences.

The closure of the James River fin and shellfish fisheries in December 1975, as a result of Kepone contamination is estimated to have resulted in a loss of commercial catches worth $12.4 million (present value) during the period, 1976 through 1981 (based on G.K. O'Mara and R.R. Reynolds, "Evaluation of Economic and Social Consequences of Restricting Fishing Due to Kepone Pollution in the James River, Virginia," Economic Analysis Branch, OPP, EPA February 1976). It should be noted that species involved here, have less commercial value per pound than the salmonoids. A continued ban on fishing for certain fin-fish species (i.e., striped bass, croaker, eel, bluefish, sea-trout and spot) for the foreseeable future seems likely, due to extreme persistence of kepone in the river bed.

Pimentel, et al. have estimated that pesticide related commercial fishery losses amount to some $5.5 million dollars annually. (D. Pimentel and J.H. Perkins, eds. Pest Control: Cultural and Environmental Aspects, Westview Press, Boulder, Colo., 1980, p. 132).

Honey bees are highy susceptable to a number of common pesticides such as carbaryl and methyl parathion. The market value of the annual honey and beeswax output of the typical honey bee colony has ranged from $35 to $65 in recent years (pg. 4 Honey Production, 1977-79), ESCS, USDA, January, 1980.

Pimentel, et al. have estimated that the annual loss to society from pesticide honey beekills and resulting reduced pollination of agricultural crops is on the order of $135 million annually (D. Pimentel and J.H. Perkins, eds. Pest Control: Cultural and Environmental Aspect, Westview Press, Inc., Boulder, Colo., 1980, p. 124). It should be noted that a good deal of this sum (perhaps as much as $110 million) is associated with lost crop output resulting from reduced pollination, not related to pollination contracts with beekeepers.

d.) Recreation Use Value

Recreational use of natural resources is conventionally measured in terms of recreation days engaged in a particular activity such as hunting waterfowl, salmon fishing, watching shore birds, or canoeing on on the Flambeau River. User willingness-to-pay is generally estimated from observed expenditures, direct or indirect (such as imputed travel cost), by persons engaged in the activity. It may include an estimate of the opportunity cost of the time the recreationist devotes to the activity. In 1970, the U.S. Department of the Interior estimated that hunters and fishermen spent a total of $7 billion dollars in pursuit of these recreation activities (Fish and Wildlife Service, "National Survey of Fishing and Hunting", U.S. Department of the Interior, Res. Publ. 95, 1970). Extrapolating this sum to 1980 on the basis of the growth in personal consumption expenditures over the 1970-80 period, yields an estimate of almost $19 billion dollars spent on hunting and fishing recreation.

Whereas there seems to be no simple functional relationship between the abundance of a fish or game species and the number of days spent in its pursuit, pesticide intrusion into fish or game habitat may be sufficient to terminate the activity altogether.

This latter sort of a situation could develop as a result of endrin ingested by migratory waterfowl this year in the Montana wheat fields. If concentrations of the pesticide exceed action levels in enough duck's tissue, the waterfowl hunting season could be cancelled in as many as 17 states in the Central and Pacific Flyways. These states account for an average of 5.29 million waterfowl hunting days per season (pg. 24, Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Annual Migratory Bird Hunting Regulation: Federal Regulatory Impact Analysis, Department of the Interior, June, 1981). Conservatively valued at $9 per day, this would imply a social cost of $47.6 million in lost recreational use.

Insofar as pesticides not intended for aquatic use frequently find their way into lakes and rivers where they seriously degrade water quality, the general recreational value of water quality becomes relevant. The U.S. Forest Service uses $69.59 as the annual value of water quality for swimming, boating and fishing per U.S. household (R.G. Walsh, "Recreational User Benefits from Water Quality Improvement", Outdoor Recreation: Advances in the Application of Economics, GTR WO-2, U.S. Forest Service, USDA, March 1977). The user value of water quality in the South Platte River Basin has been estimated at $56.68 per year, or $3.76 per use day, based on 15 use days per year (R.G. Walsh, D.A. Greenley, R.A. Young, J.P. McKean and A.A. Prato, "Option Values, Preservation Values and Recreational Values of Improved Water Quality: A Case Study of the South Platte River Basin, Colorado", U.S. EPA, January, 1978).

e.) Option, Existence and Bequest Values

As far as can be determined, option, existence and bequest values have not been estimated for individual plant and animal species. The estimates of these values that have been done have focused on water quality.

Walsh, Greenly, Young, McKean and Prato, in the study cited above, estimated the option value of water quality in the South Platte to be $22.60 per year for user households. The addition of option value to use value increases the benefits of water quality to user households by 40 percent. Existence and bequest values estimated for households that did not use, nor ever plan to use, the South Platte for recreational purposes were $24.98 and $16.97 respectively. Thus, it appears that households that had no intention of making use of the river basin, valued improvements in its water quality at $41.95 per year, or 53 percent of the value user households placed on such improvements.

f.) Comparative Ecological Impacts

It is difficult to be very precise about how the alternative approaches for generating information on pesticide products will ultimately effect the level of ecological risk. Presumably, the reduction in risk to the environment is an inverse function of the amount and quality of non-target species, environmental fate and product chemistry test data generated. In that regard, the comprehensive data requirements option will generate the most good test data, and the self-certification option will generate the least. Among the options in the middle range, the regulatory requirements would probably produce somewhat more quality ecological test data than either the current reference guidelines or the provisional registration alternative. Consequently, one can conclude (see Table IX-4) that the greatest reduction in risk of ecological damage would result from the adoption of the comprehensive data requirements option. Slightly smaller reductions in ecological risk would result from adopting the regulatory requirements, and still smaller reductions in such risks would follow from adopting either the reference guidelines or provisional registration options. Least risk reduction, or the highest levels of ecological damage, can be expected to result from adoption of self-certification option. This stems from the fact that on their own firms have little economic (liability) incentive to do non-target species testing well, if they do it at all.

V. COMPLIANCE COST ANALYSIS OF DATA REQUIREMENTS

Implementation of any of the five alternative approaches involves costs of generating and submitting testing information which are costs directly associated with Agency requirements, and other costs indirectly related to requirements. This section presents estimates of the direct compliance costs under various scenarios, along with costs that are indirectly affected. Some of the major indirect costs are estimated quantitatively while others can only be discussed qualitatively because of insufficient data to make projections.

The calculation of direct compliance costs involves estimation of unit costs of individual studies and estimation of the number of studies expected to be required on an annual or other time-period basis. Unit cost information has been collected from several sources including contract (for fee) laboratories and pesticide industry firms which have their own testing facilities. The information collected was then narrowed into consensus ranges.

The approach used in the cost analysis was to estimate (a) total costs of meeting Agency requirements under each of the alternatives for specified scenarios of program activity during a 10 year period (1982/91) and (b) incremental compliance cost impacts of shifting from the baseline of the current program, which has compliance costs comparable to alternatives #1 and #2, reference guidelines and data requirements. Although the current program is not the same as either alternative #1 or #2, it has costs about the same as those two options.

A. Data Costs for Registration of Pesticides Using Alternative Approaches

1. Active Ingredients

To estimate the annual costs of data requirements for new chemical active ingredients under alternatives #1 and #2, the approach taken was to describe two model new chemicals and predict the data requirements necessary for chemicals having those model characteristics. As a generalization, the major distinguishing features of chemicals as they relate to triggering the need for data, are whether the chemical is intended for use on a food or feed crop and whether it is to be used outdoors. The model chemicals selected for predictive purposes are: 1) a food crop use pesticide with at least four food use sites; and 2) a non-food use pesticide that has some limited outdoor use possibilities. These two models were chosen to be representative of chemicals with respect to the volume of data typically required to register new food use and non-food use pesticides. The range represented by the two models is not intended to reflect the highest possible costs nor the lowest possible.

Under alternative #3, self-certification, predictions of specific tests that might be done would be very speculative. It is known from the surveys published by the National Agricultural Chemical Association (NACA) that the industry does significant testing beyond that required by EPA. A logical presumption is that the industry would do a significant amount of testing regardless of regulatory requirements. A reasonable conclusion is that outlays for testing new active ingredients would, at a minimum, be 50% of the estimates for alternatives #1 and #2. The maximum for alternative #3 would be the same as for alternatives #1 and #2.

Alternative #4, comprehensive requirements, would involve totalling all testing costs of studies identified for alternative #2, but without waivers. The costs would be 50% higher than for alternatives #1 and #2. Alternative #5, provisional registration, is expected to have costs falling in between the low end of alternative #3 and alternatives #1 and #2. For this analysis, it is assumed that 75% of the costs under alternatives #1 and #2 would occur under actual implementation. The unit costs of the various test requirements used in deriving the costs in Table V-1 are presented in Appendix 1. Table V-1 summarizes the data costs for a new active ingredient by alternative approach.

2. Formulated Products

Section 3(c)(2)(D) of FIFRA, as amended, states that an applicant who purchases a registered product for purposes of formulating that product into an end-use product (formulation) shall not be required to submit or cite data on the safety of the purchased product.

However, in addition to the testing performed by basic producers, data requirements have also been established in the regulatory requirements for end-use formulated products. Data on product chemistry and acute toxicity are specified for individual formulated products as a generality. Other testing may be needed depending on the nature of the formulated product. These testing requirements are those that would typically be met by the formulator registrant and not the producer of the active ingredient, when these companies are not the same. The estimate of of $24,700-$66,000 is obtained for both alternatives #1 and #2. Table V-2 summarizes the data costs for a formulated product, independent of the testing costs for active ingredients for each alternative approach.

B. Reregistration Data Costs

1. Scenarios for 1982-91

The Registration Standards (RS) programs's mode of operation is to collect the existing test data on a chemical and the formulated products produced using that chemical. These test data are then reviewed with respect to how well they satisfy the requirements for

Table V-1

Basic Producer Testing Costs for
New Ingredient by
Alternative Approach

Alternative	Food Use Chemical	Non-Food Use Chemical
	------------------Dollars	----------------------------
# 1.	1,811,900 - 2,874,200	364,500 - 704,000
# 2.	1,811,900 - 2,874,200	364,500 - 704,000
# 3.	905,950 - 2,874,200	182,250 - 704,000
# 4.	2,717,850 - 4,311,300	546,750 - 1,056,000
# 5.	1,358,925 - 2,155,650	273,375 - 528,000

Table V-2

Formulated Product Testing
Costs by Alternative Approach

Alternative	Formulated Product All Uses
	-----------Dollars-------------
# 1.	24,700 - 66,000
# 2.	24,700 - 66,000
# 3.	12,350 - 33,000
# 4.	37,050 - 99,000
# 5.	18,525 - 49,500

registration. The review process combines the information known about a chemical and policies of the Office of Pesticide Programs into a regulatory position on the registerability of a chemical for the chemical's intended use sites.

One variable in the Registration Standards process is the number of reviews that will be undertaken annually. In large measure, the rate of reviewing chemicals depends on resources available to the Registration Standards program. Alternative scenarios are used here to reflect the level of resources expected to be available in the future. Should more resources become available, output would be higher.

Another scenario within the Registration Standards program under development by OPP is the initiation of data call-in actions for chronic effects toxicology studies (Chronic Feeding, Oncogenicity, Reproduction and Teratology). In this program, registrants would be notified that chronic effects toxicology studies will be required to support the registrations of their products.

Data call-in and Registration Standards are part of the same process for expeditiously completing the reregistration of all currently registered pesticide products. The data call-in notices and the RS schedule are based on the same priorities in selecting individual chemicals for processing. As the data base for the chronic effects studies is established, the chronic effects area should no longer be a significant source of data gaps. Therefore, as long as data call-in generally is coordinated with the RS schedule, after 3 or 4 years data call-in will not cause the industry to incur costs at a different overall rate than the RS program, i.e., 25 to 40 chemicals per year.

2. Projected Costs, 1982-91

The annual costs of data for reregistration under the five alternative approaches will depend on which scenario occurs concerning the pace of the Registration Standards program, waiver policy, and the continuance of data call-in under the Registration Standards program. Costs to be incurred are net of costs previously incurred under various scenarios, that is, there are currently available data in EPA files that are useful to support registration. The cost of this old data is not counted in any of the 5 approaches here. In order to cover the range of annual costs over 1982-91, three projections have been made. One assumes that the development of standards will begin at 15 chemicals per year and increases to 25 chemicals per year. Data call-in is not assumed to occur. The second projection assumes a constant rate of 25 standards developed per year, and that the data call-in procedure is used. A third projection assumes 40 standards developed and a data call-in procedure is used.

For the first twelve chemicals that have data gaps identified in either published or draft standards documents, costs for data development to be incurred by basic producers were $9.3 million and by formulators were $2.7 million for a total of about $12.0 million. For data call-in, the average cost per chemical for these four chronic effects studies would be about $560,000. At 50 chemicals slated for data call-in per year in the initial years of the program, the cost of studies to be initiated would be about $28 million. These costs do not reflect an addition to the total costs of the Registration Standards program.

C. New Registrations

1. New Chemicals

For applications to register products containing new active ingredients, there is little that the Agency can do to directly affect the number submitted annually. For purposes of this analysis, the assumption is made that the applications for registration of new chemicals will continue at the current rate of about 15 chemicals approved each year.

2. New Formulated Products from New Chemicals

In addition to costs incurred by the basic chemical producers, there would also be costs incurred by formulators of the new chemicals. (The firms may be the same). In Table V-2, the expected costs for a new formulation of a new chemical have been estimated to range from $12,350 to $99,000 depending on the alternative approach. These are the costs in addition to the studies performed by basic producers using either technical grade material or typical formulated product preparation. It is assumed in this analysis that 20 new formulated products per new chemical would be registered in the early years of the new registration.

3. New Formulated Products from Old Chemicals

In addition to currently registered products and new formulated products from new chemicals, the data requirements will also affect new formulated products from old chemicals. Costs of $2,500-$5,000 per product are assumed for each alternative since basic product testing is expected to be done under all alternative approaches.

The Agency currently registers about 3,000 new products containing old chemicals annually. If this rate of registration continues, the annual costs for data would be $7.5 - $15.0 million for this category of products for each alternative.

D. Direct Data Costs for All Registrations

Summarized in Table V-3 are costs directly associated with complying with data requirements for existing and new pesticides during the 1982/91

Table V-3

Costs Directly Associated with Meeting Data Requirements for Reregistration and Registration of New Pesticides, by Scenario and Alternative Approach, 1982/91

Scenario/ Alternative	Cost/year	10 Year Total
	- - - - - - - - - -$ millions	- - - - - - - -
15-25 stds/yr.		
Alt. # 1	46.3-79.0	533.0-760.0
Alt. # 2	46.3-79.0	533.0-760.0
Alt. # 3	27.2-79.0	307.0-760.0
Alt. # 4	65.9-111.9	764.0-1,074.0
Alt. # 5	41.2-71.6	482.0-686.0
25 stds/yr. with data call-in		
Alt. # 1	56.3-107.0	661.0-888.0
Alt. # 2	56.3-107.0	661.0-888.0
Alt. # 3	32.2-107.0	371.0-888.0
Alt. # 4	80.9-153.9	956.0-1,266.0
Alt. # 5	51.2-99.6	610.0-814.0
40 stds/yr. with data call-in		
Alt. # 1	71.3-122.0	811.0-1,038.0
Alt. # 2	71.3-122.0	811.0-1,038.0
Alt. # 3	39.7-122.0	446.0-1,038.0
Alt. # 4	103.4-176.4	1,181.0-1,460.0
Alt. # 5	66.2-114.6	760.0-964.0

period. Costs range from a low of \$27.2-79.0 million for the lowest cost scenario under self-certification (#3) to \$103.4-176.4 million per year for the most costly scenario under comprehensive data requirements (#4).

E. Indirect Industry Costs

In addition to affecting the direct compliance costs of generating data in support of registration, the five alternative regulatory approaches affect indirectly other components of costs borne by the pesticide industry registrants. Costs of interacting with EPA to register products and the cost of managing the testing of chemicals are the largest indirect cost item. The costs associated with resolving RPAR's (review of chemicals potentially presumed to cause unreasonable adverse affects) would be expected to vary inversely with the stringency and cost of the alternative regulatory approaches. The need for inspections for enforcement purposes would also be expected to show the same pattern. There is evidence that a significant reduction in federal regulation, such as under option 3, self-certification might cause many States to increase their own requirements of pesticide producers. Thus the regulatory approaches would indirectly affect the cost of compliance with state regulations. Table V-4 summarizes the projected levels of costs that would be indirectly affected/changed by adopting each of the five alternative approaches. Table V-5 summarizes the direct compliance costs and the costs indirectly affected by alternative approach and registration scenario.

There are conceivable other indirect changes in the costs to the industry. For example, changes in risk for product liability would likely be inversely related to the stringency of regulation. As a corollary insurance premiums would conceivably be affected. No data were available to serve as a basis for estimating changes in other cost areas that might be indirectly affected.

In Section VI of this report, a summary is presented of all pesticide industry costs incurred as a result of federal regulatory requirements under FIFRA, FFDCA, and RCRA to place into perspective all regulatory related costs which can be estimated.

F. Change from Current Practice to Alternative Approaches

An important aspect of the estimated costs of the several alternative aproaches is the level of change from what is the cost of current requirements. The Agency, as previously stated, now requires data in support of registration of pesticide products. There is general knowledge on the part of the industry as to what data EPA now expects, and these data are being sent to the Agency as part of the normal interaction between the Agency and registrants. Current practice is best described in alternative #1. The changes in direct industry compliance costs from moving from current practice to alternative #1 (and #2) is thus zero. Table V-6 provides the net changes in moving from current practice to the other approaches analyzed here.

Table V-4

Projected Cost Areas Indirectly Affected
by Alternative Approaches to Data Requirements,
1982/91, Per Year

Cost Area	Option #1 Reference Guidelines	#2 Regulatory Requirements	#3 Self-Certification	#4 Comprehensive Data Requirements	#5 Provisional Registration
	$ Million				
Registration Activities and Overhead a/	19.4	19.4	11.7	22.1	18.2
RPAR Data	5.5	5.5	8.5	0.5	6.5
RPAR Rebuttal Administration	2.1	2.1	3.1	0.5	2.6
Inspection	0.3	0.3	0.6	0.3	0.3
Compliance with State Requirements b/	-	-	7.5		
Total	27.3	27.3	31.4	23.4	27.6

a/ Includes costs of interaction with EPA to obtain registration and costs to manage testing required to support registration.

b/ The cost for compliance with state requirements is stated in terms of changes from an unspecified baseline.

Table V-5

Total Costs of Data Requirements by Registrants (Costs Directly and Indirectly Related to EPA Requirements), for Reregistration and New Registrations, 1982/91 Period, Per Year

Scenario/ Alternative	Range	Midpoint
	- - - - - - - - -$ Million- - - - - -	
15-25 stds/yr.		
Alt. #1	73.6-106.3	90.0
Alt. #2	73.6-106.3	90.0
Alt. #3	58.6-110.4	84.5
Alt. #4	89.3-135.3	112.3
Alt. #4	68.8- 99.2	84.0
25 stds/yr. with data call-in		
Alt. #1	83.6-134.3	109.0
Alt. #2	83.6-134.3	109.0
Alt. #3	63.6-138.4	101.0
Alt. #4	104.3-177.3	140.8
Alt. #5	78.8-127.2	103.0
40 stds/yr. with data call-in		
Alt. #1	98.6-149.3	124.0
Alt. #2	98.6-149.3	124.0
Alt. #3	71.1-153.4	112.3
Alt. #4	126.8-199.8	163.3
Alt. #5	93.8-142.2	118.0

Table V-6

Change in Estimated Industry Compliance Costs from Current Program to Alternative Approaches, 1982/91, Per Year

Scenario/ Alternative	$ Millions Per Year
15-25 stds/yr.	
Alt. #1	0.0
Alt. #2	0.0
Alt. #3	-5.5
Alt. #4	22.3
Alt. #5	-6.0
25 stds/yr. with data call-in	
Alt. #1	0.0
Alt. #2	0.0
Alt. #3	-8.0
Alt. #4	31.8
Alt. #5	-6.0
40 stds/yr. with data call-in	
Alt. #1	0.0
Alt. #2	0.0
Alt. #3	-11.7
Alt. #4	39.3
Alt. #5	-6.0

VI. PESTICIDE INDUSTRY IMPACT ANALYSIS

A. Pesticide Industry Overview

The pesticide industry is a generally profitable and growing sector. Sales and production have trended upward since its beginning during and after WW II as DDT led the way toward the synthetic organic pesticide industry we know today. The U.S. is the largest single market in the world, with about one-third of the world's pecticide sales at the user level. The primary component of the industry is a nucleus of about 30 major basic producers of pesticides. These generally are a part of larger multi-national chemical or petroleum corporations, with production and marketing facilities worldwide. This group of firms is noted in Figure VI-1 along with other key profile features of the pesticide industry, at the marketing and user levels.

The focus of this section of the report is upon the basic producers, because these firms conduct the majority of pesticide safety testing, thereby being the primary group impacted by the alternative approaches to data requirements. The producing industry employs approximately 15,000 people in the production of up to 1,400 different chemical active ingredients. R&D is an important aspect of the industry, resulting in 10 to 20 new active ingredients each year (more than 140 since 1970). Each year, about 200 new firms register pesticides with EPA for the first time. These are primarily formulators (or distributors) who are marketing products containing active ingredients manufactured by one or more of the basic producers.

Presented in the remainder of this section of the report is an analysis of the alternative approaches as they would impact upon market structure, competitor behavior (conduct) and performance, generally as currently defined (Scherer, 1980).

B. Producer Level Profile and Impact Analysis

1. Current Profile

The profile of producers is subdivided into three parts: market structure (Figure VI-2), competitive behavior (Figure VI-3), and performance (Figure VI-4). The basic taxonomy for these three parts is derived primarily from *Economic Profile of the Pesticide Industry* prepared by ICF Incorporated (ICF Inc., 1980a). The taxonomy serves both as the profile of the industry and as the basis for comparison of the regulatory alternatives under consideration.

2. Impact Analysis

a. Production Costs and Prices

Compliance costs to registrants impact upon production costs, and in turn, prices charged for pesticides. The compliance costs for all registrants for the five alternatives are as follows:

Figure VI-1

U.S. Pesticide Production and User Sectors

Key Profile Parameters

(Approximate Values)

Basic Production Level	Marketing Level	User Level
30 Major Basic Producers	3,300 Formulators	1 - 2 Mil. Farms
100 Other Producers	29,000 Distributors and Establishments	75,000,000 Households 40,000, Commercial Pest Control Firms
1,400 Active Ingredients Registered	35,000 Formulated Products Registered at Federal Level	(Several million) Other Industry/ Government Users
1,000 Active Ingredients in Production		
200 Major Active Ingredients in Production	200 New Firms Registering Pesticides/Yr.	
15 New Active Ingredients/Yr.		
15,000 Employment		

1980 Market Estimates

Production	1.5 bil. lbs.	U.S. Active Ingredient	1.2 bil. lbs	Value of Purchases	$5.8 bil.
Exports	0.4 bil. lbs.	Agricultural Usage Share	72%	Agricultural Share	62%
Imports	0.1	Ind/Govt. Share	21%	Ind/Govt. Share	24%
Value of U.S. Sales	$3.3 bil.	Home/Garden	7%	Home/Garden Share	14%

Figure VI-2

Market Structure Profile of U.S. Pesticide Producing Industry

Factor	Key Word Description	Explanation
1. Number of Firms	small number	30 major manufacturers of active ingredients and 100 small scale producers.
2. Seller Concentration		
a) Industry Sales	oligopoly core and monoplistically competitive fringe of firms; moderately high and increasing as industry definition narrows	The top four firms produce 35% to 40% of total production and the top 20 firms produce the bulk (97%) of the pesticides.
b) Market Level Sales	highly concentrated within specific site/classes particularly within regions	For specific site/classes of pesticides, particularly region specific (i.e., cotton/weevil in California), the market often is very concentrated tending toward monopoly.
c) Industry R&D	highly concentrated	Less than 10 firms account for 50% of R&D.
3. Product Differentiation	highly differentiated products, especially proprietary items	Each ingredient is a distinct chemical and often unique in efficacy, persistence and toxicity to crops and "non-targets". Sellers further differentiate by offering ancillary goods and services and by contracting product exclusivity, thus preventing distributors from handling competing products.

Figure VI-2—continued

Market Structure Profile of U.S. Pesticide Producing Industry

Factor	Key Work Description	Explanation
4. Barriers to Entry		
a) Economies of Scale in Production	not significant generally	Examples of wide differences in plant size for the same product.
b) Capital Requirements	highly capital intensive	Ratio of value added to gross book value of assets about .61 in comparison to all manufacturing industries ratio of 1.30.
c) Research and Development	high R&D expenditure requirements	Ratio of R&D expenditure to sales about 8% compared to pharmaceutical and heavy chemicals of 10% and 2-4% respectively.
d) Patents	high degree of protection on new products	Patents are important particularly for new products. About 3/4 of all products in sales dollars are proprietary.
5. Integration	not highly integrated by ownership ownership	Producers tend not to be formulators' however defacto integration can exist by contracts between producers and formulation/distribution.
6. Level of Information of Buyers and Sellers	low: limited published market data; buyers not particularly well informed	Most of the market data available within producers is treated as proprietary.

Source: ICF Inc., Economic Profile of the Pesticide Industry; August 1980.

Figure VI-3

Competitive Behavior Profile of U.S. Pesticide Producers

Factor	Key Word Description	Explanation
1. Pricing Patterns	Oligopolistic/ monopolistic firms influencing market prices and sales volume by their individual actions	Firms can exploit inelastic price demand relationship. High degree of seller concentration and integration; less than optimum information available between buyers and sellers.
2. Non-Price Behavior		
a) Investment	Quite responsive to demand	Producers generally respond well to increasing demand; during the past 20 years (thru 1976), substantial additional production capacity was built.
b) R&D	Heavy emphasis on new product discovery	Competitive advantage is sought through R&D discovery of new products for which patent rights restrict competition and sometimes allow near monopolistic market development.
c) Product Strategy and Advertising	High degree of product differentiation	Intensive promotional activities to create brand preference including trial or free product testing, and subsidizing application equipment purchase and contractually limiting formulator processing of competitive products.

Source: ICF Inc., Economic Profile of the Pesticide Industry; August 1980

Figure VI-4

Performance Profile of the U.S. Pesticide Producers

Factor	Key Word Description	Explanation
1. Prices	Favorable price performance	Price declined during the 50's and 60's attributed to process improvements for new products. Price increases in the 70's associated with inflationary conditions and petroleum prices. Prices of individual products often give no evidence of responding to the changing balance of supply and demand and of price changes in competing pesticides suggesting that the pesticide producers tend to be oligopolistic. Older products are considered commodities and are incorporated in many products forcing prices down.
2. Profits	Medium to high	Return on sales about 6.6% and return on equity investment about 16%. Profits often very high on individual products or divisions, which are masked by overall firm profit rate.
3. Production	Growth and industry	About 1.4 billion lbs. in 1980, an increase of 45% over 1964 production. Value added per production worker is nearly double all chemical industries.
4. Innovation a) New Chemical Registration	Frequent new products/chemicals	Average annual new chemical registration with EPA was 14 per year between 1971 and 1980; no consistent trend down or up.
b) Research and Development Effort	High degree of effort	During the past 10 years, R&D expenditures kept pace with sales. (R&D expenditures are about 8% of 1980 gross sales); more than most other industries.
c) Product Development Costs	High	Reportedly $50-70 million per new chemical.
d) Development Time for New Chemicals	Rather long	About 85-95 months from time of pesticide discovery to product marketing.

Source: ICF Inc., Economic Profile of the Pesticide Industry; August 1980.

	Cost of Compliance/Yr. $Millions	
	Total	Difference from Current Baseline
#1 Reference Guidelines	109.0 (83.6-134.3)	0
#2 Regulatory Requirements	109.0 (83.6-134.3)	0
#3 Self-Certification	101.0 (63.6-138.4)	-8.0
#4 Compliance Data Requirements	140.8 (104.3-177.3)	+31.8
#5 Provisional Registration	103.0 (78.8 - 127.2)	-6.0

A majority of these costs would be incurred by the basic producers, who also do most of the formulating. Possibly 80-90 percent of these costs would be incurred by the 130 firms which engage in basic production. Specific data are not available to permit a precise breakout of compliance costs for firms which are only formulators.

Current compliance costs costs to firms engaged in pesticide production in the range of $100 million per year are obviously significant, even through they equal only about 3.0 percent on sales at the production level of the industry ($3.3 billion in 1980). A compliance cost of $100 million would equal about one fourth of industry producer R&D, $395 million in 1980, (NACA, May, 1981). Alternatives #3 and #5 would reduce compliance costs by less than $10 million per year, which could be quite a nominal impact on producer prices (0.3 percent). Comprehensive data requirements would increase compliance costs measureably, by more than $30 million, this would not be evenly distributed, as much of the R&D is by a few firms. For example, in 1980, only 13 firms accounted for 74 percent of total R&D (NACA, May, 1981).

In conclusion, pesticide prices now reflect data costs in the range of the Agency proposal and the alternatives would necessitate rather nominal price changes.

b.) Profits and Development Time.

A reduction in time to registration is associated particularly with self-certification and provisional registration. For a typical product, there is a projected decline of resubmissions of data from registrants and the more timely processing of applications. The projected reduction in time to registration can impact profits, which is illustrated in the detailed cost/benefit analysis report (EPA/OPP, May 15, 1982). Reduction in time to registration would tend to increase the accumulated earnings between the pesticide investment breakeven point and the time when the product patent expires, thus increasing returns on investment.

The uncertainty of continuance of a registration is a major concern of industry. The probability of a chemical registration being disallowed or cancelled after RPAR review is reduced by providing the data, particularly with registration requirements and comprehensive data requirements. This enables EPA, as well as industry, to more thoroughly screen out problematical chemicals.

The impacts of the alternatives upon the time required to obtain EPA registrations are as follows: Alternative #1 would not cause major changes; Alternative #2 could reduce the time about 5 months on the average and potentially as much as an additional 10 months. Alternative #4 would increase the time over present guidelines, by 25 months. Alternative #5 (provisional registration) would shorten the time similar to the reduction estimated for Alternative #3, about 15 to 25 months. In addition, by eliminating EPA review, the time to registration determination could be decreased if some tests were abandoned completely (as may be the situation under Alternative #3, self-certification). To the extent that the alternatives would reduce the time to registration, they could serve to increase the incentives for R&D investments, and possibly increase the number of new registrations.

c.) Production

The analysis of the impacts under the alternatives reviewed indicates that the market for certain low volume active ingredients would not justify the expense of generating the required data with comprehensive data requirements. A minimum of $500,000 to $1 million in annual sales of an active ingredient (equivalent to several hundred thousand to one-half million pounds of production) would seem to be required depending on profit rates and market strategies. For the products in which sales volume and profits do not justify the expense of generating the required data, the various waivers would most likely apply particularly for the non-food and non-feed crop use products. The impacts on small volume active ingredient producers would be reduced by the waiver of data requirements for certain chemicals as provided for in all the alternatives reviewed except #4.

For Alternative #4, where all waivers are disallowed, many small volume product lines would be abandoned and there would be a redistribution of performance factors, perhaps for the 100 small volume firms. The production (and perhaps profits and employment) could be reduced among small volume producers and increased among large scale producers where there are viable substitutes for the abandoned speciality products.

When Registration Standards guidance packages are sent to registrants, they are informed of the data gaps which they must fill in order to maintain their registrations. As of October 1981, responses from registrants relative to nine RS chemicals have been received. Of all active ingredients associated with the 9 RS chemicals, the voluntarily cancelled products accounted for less than 0.1% of the combined production volumes of those chemicals. In essence, the initial responses to the Registration Standards program caused insignificant effects on the markets for individual chemicals and pesticides as a whole.

Making projections of the level of future voluntary cancellations under the five alternative regulatory approaches can only be done tentatively. Alternatives #1 and #2, reference guidelines and regulatory requirements respectively, have been concluded as having essentially the same costs. Hence, voluntary cancellations would be the same under each alternative. As chemicals having food and feed crop uses become dominant in the RS program, it is likely that more significant data gaps will be found and hence the data costs for individual chemicals might be more burdensome for some of the lower sales volume chemicals and end-use products.

Under Alternatives #1 and #2, as many as 100 or more of the 600 RS chemicals which Registration Standards are to be developed may not be reregistered. As large as this figure may seem, a loss of 100 active ingredients would affect mostly low sales volume products. The loss in total volume of pesticides used would likely be less than 5% after the RS program has proceeded through the 600 chemicals.

Under Alternative #3, self-certification, few if any active ingredients and associated products would be voluntarily cancelled. Under an approach where waivers would not be granted, as in Alternative #4, comprehensive requirements, it is estimated that as many as 300 of the 600 RS chemicals might not be reregistered. The withdrawal of these chemicals would alter as much as 10-15% of the total pesticides marketed annually. Under Alternative #5, provisional registration, the voluntary cancellation level would be the same as for Alternatives #1 and #2.

d.) Industry Concerns about Impacts on Innovation

Innovation through research and development creates new products and new uses for existing products. User benefits are associated with pest control, generally for public health, crop production and aesthetic appeal and, in addition, to replace products for which there is increasing pest resistance or environmental concern. Producers benefit through increased profits which in turn motivate innovation. New products enable innovators to obtain greater profits through the competitive advantage gained by early market entry and patent protection.

The impact of regulations on the innovative process is seen by industry as negative as is expressed in a recent CAST Report (CAST, 1981) in which the increase in EPA regulation activities were associated with the increase product development costs. Industry, through the referenced report, specifically claims that the increase in R&D expenditures associated with registration will effect a relative decrease in R&D expenditures for product development. The concern is that there will be an eventual decline in the introduction of new products. It is argued that the newly emerging products used in IPM and the biological control agents which have very limited and specific use patterns will be particularly affected, along with other small volume or minor use products.

Claims are made in the referenced CAST Report that R&D expenditures are diverted from product development activities such as synthesis, screening and field testing to registration-related activities and hence these expenditures are unproductive in terms of new product innovation. They also claim that the current trend is to direct R&D activities to develop broad spectrum products where there are large scale market potentials rather than products with more specific or narrow areas of end use. Reportedly, the incentive for R&D investment is reduced by regulatory activities and all but eliminated for small volume and minor use cases.

In the CAST Report, it is maintained that, under these circumstances, a decline in innovation is likely and, indeed, the CAST Report claims there has been a decline in R&D productivity. Furthermore, it is argued that the EPA data requirements will divert technical and scientific capacity from developmental i.e., synthesis, screening and field development of new materials, to regulatory activities with associated loses in the development field; that innovation for limited use products, particularly for the newly emerging areas of IPM and biological control, will be curtailed, and that these difficulties will encourage firms to develop and market products in foreign countries where regulations are not as restrictive, resulting in actual disinvestment. If these contentions are realized, a reduction in new products entering the market will further increase industry concentration and exacerbate the already concentrated pesticide market structure.

EPA pesticide registration does contribute to industry costs by requiring compliance with the registration regulations. Industry direct costs range from $1.8 to $2.8 million per major crop chemical. The major indirect costs are associated with the potential revenues foregone during the time delays in complying with EPA's registration procedures. These costs can be significant, and are generally passed on to users in the form of price increases. If these costs were to be borne by all applicants in all cases, they could effectively stop innovation, product development and registration for low volume or minor use pesticides--in effect the contentions of industry previously enumerated would be realized. However, there is no evidence that they have reduced the industry's innovative activities through R&D, particularly for the major crop high volume pesticides.

Current regulations allow data waivers for products where volume and use do not cause environmental concerns. These waivers are specifically applicable to minor use and small volume IPM pesticides. Subpart "M" of the regulatory guidelines, "Data Requirements for Biological Pesticides" effectively provides a waiver for the data requirements for the biologicals. Thus, these waivers, implemented according to the existing procedures will greatly reduce the negative impact of these regulations on low volume and minor use products, removing much of the industry's cause for concern previously discussed.

A conclusion that little if any reduction in innovations can be related to the current regulatory structure in the pesticide industry seems appropriate. This conclusion is corroborated in a study by the Conservation Foundation (Conservation Foundation, 1980). The Study has drawn three significant conclusions:

> First, innovation in pesticides has not been adversely affected by regulation.
>
> Second, of the regulation-related factors that influence a firm's decision to innovate, time delay is probably the most important.
>
> Third, the impact of regulatory requirements thought to fall much more heavily on small firms than on large ones was not corroborated.

The conclusions of a recent report by the Office of Technology Assessment (OTA, 1981) are generally consistent with the Conservation Report. The OTA report adds that "while FIFRA tends to reinforce a pattern of product innovation targeted toward large markets, the level and pattern of pesticide innovation are determined primarily by market factors." Thus while EPA regulations clearly impose a significant cost factor ($1.8 to $2.8 million), these costs represent a small part of the total costs of commercially developing a pesticide ($20 to $70 million). Furthermore, it is an arguable matter if these costs can be attributed to the regulatory process—some may be incurred as prudent business behavior. These costs may increase the barrier to entry, but there is little evidence that these factors have diminished industry's innovative attempts through R&D expenditures. While, the conclusion presented in the OTA report is that entry barriers created by EPA regulation are likey to have their greatest effect on small firms, they did not consider the allowance of waivers for small volume pesticides and the special handling allowed for the biorationals. The CAST report acknowledges the potential lessening of the negative impacts of the regulatory guidelines on small volume producers since the 1978 FIFRA amendments but states that the effects of these provisions have yet to be demonstrated. Perhaps regulatory actions resulting from the implementation of the mentioned waivers may lessen the industry's concerns about the impacts on the small volume producers.

e.) Impacts on R&D Expenditures

Due to the costs for developing a new pesticides, only a relatively small number of individual markets are large enough to justify the development of a new pesticide. In general, pesticides are initially developed and registered for major crops and subsequently tested and registered for minor crops. This characteristic is generic to the industry and not clearly associated with regulatory procedures.

The total R&D expenditures are estimated at $395 million in 1980 representing 8.5% of sales (Table VI-1). While this is a significant increase from the $70 million spent in 1970, it represents a relatively constant rate of R&D expenditures as a percent of sales.

The CAST Report cites as a factor in these increased R&D costs a decline in pesticide innovation associated with a declining R&D productivity in the pesticide industry. This decline in productivity is (according to the CAST Report) associated with the increase in R&D expenditures in the registration-related activities, e.g., the various toxicology, metabolism and environmental residue tests required to obtain registration. The implicit argument is that since total R&D expenditures have remained relatively constant at about 8% of sales, the allocations for the three general R&D activities deemed essential to new product development may suffer, (i.e., while total R&D expenditures have kept up proportionately with sales, expenditures allocated to product synthesis, screening, field testing and formulation and process development have not kept up with sales proportionately). The CAST Report cites as a conclusion that the number of compounds screened per employee has declined. However, they also cite that the number of compounds screened for pesticide activity rose between 1967 and 1978.

Registration related activities have indeed increased from about 20% of the total R&D expenditures in 1970 to about 30% in 1980. The cost increase associated with registration required tests, aside from inflation, is attributed partially to a change in testing protocols and laboratory standards during the same period. Since responsible firms would presumably perform substantial testing of new active ingredients even in the absence of EPA requirements, it is difficult to determine the precise share of testing costs due strictly to regulations.

R&D expenditures may not be significantly affected by the proposed alternatives studied, except under Alternative #4. To the extent that specialized markets for small volume products would be restricted (in contrast with the third conclusion cited from the Conservation Foundation), there may be less incentive to invest in R&D. The small volume specialty market affected under Alternative #4 is not only the purview of the small scale producer but it also provides all firms with a profit source both during periods before a product reaches market maturity while market development is occurring and after market maturity, before a product is completely phased out of production. Since the R&D activities are already heavily concentrated within the large scale producers as previously discussed, the reduction in R&D investment incentives even under Alternative #4 might not impact significantly the total amount of industry R&D expenditures.

The above review of cost, time and related impacts upon the pesticide producing industry indicates that structure, conduct and performance outcomes under the five alternatives would be as indicated by key word descriptors in Figure VI-5. Impacts of shifting from the current program would not be highly significant except for #3 and #4.

Table VI-1
Pesticide R&D Expenditures and Sales: Basic Producer Level
1970-1980, Current Dollars

Year	Registration - Related R&D Expenditures		Total R&D Expenditures	Basic Producer Sales	Registration Related R&D Expend. As Percent of Total R&D		Total R&D Exp. As Percent of Sales
	Including "All Other" 1/	Not Including "All Other" 2/			Including "All Other"	Not Including "All Other"	
	Million Dollars				Percent		
1967	10	9	52	639	19.2	17.3	8.1
1968	10	9	56	691	17.9	16.1	8.1
1969	11	10	65	693	16.1	15.4	9.4
1970	13	12	70	722	18.6	17.1	9.7
1971	18	17	88	1,044	20.5	19.3	8.4
1972	21	20	98	1,154	21.4	20.4	8.5
1973	26	25	111	1,417	23.4	22.5	7.8
1974	39	35	135	1,956	28.9	25.9	6.9
1975	45	41	160	2,471	28.1	25.6	6.5
1976	60	44	195	2,576	30.8	22.6	7.6
1977	78	60	250	3,115	31.2	24.0	8.0
1978	89	69	289	3,607	30.8	23.8	8.0
1979	104	78	332	4,154	31.3	23.5	8.0
1980	119	94	395	4,658	30.1	23.8	8.5

Figure VI-5

Summary of Economic Outcomes in the Pesticide Producing Sector from Alternative Approaches in Generating Safety Information on Pesticide Products

	#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self-Certification by Registrants	#4 Comprehensive Requirements	#5 Provisional Registration
a. Producer Structure	medium to high concentration/ entry barriers	medium to high concentration entry barriers increased slightly	medium concentration/ entry barriers	high concentration/ entry barriers	medium concentration/ reduced entry barriers
b. Producer Competitive Behavior	oligopolistic, with occasional rivalry, especially during periods of declining demand	oligopolistic, with some proprietary products dominating markets	oligopolistic, but with increased competitive rivalry especially on non-patented products	oligopolistic, with powerful firms dominating competitive interaction	oligopolistic, with some increased rivalry of new products with old ones
c. Producer Performance	medium to high profits, R&D and product choice	medium to high profits and R&D; some loss in product choice possible	medium profits; R&D would suffer; product quality could suffer; reduced time for registration.	very high profits; reduced product choices with abandonment of small value products	Medium to high profits; R&D incentives improved for new active ingredients due to earlier commercialization
d. Small Firm/Impacts	moderate cost impacts, except where waivers are disallowed	moderate cost impacts, except where waivers are disallowed	minimum impacts	major impacts due to no waivers	moderate cost impacts, except where waivers are disallowed

C. Formulator Level Profile and Impact Analysis

1. Current Profile

The economic profile of the U.S. pesticide formulators is described in terms of market structure and competitive behavior in Figures VI-6 and 7.

2. Impact Analysis

Market structure conditions, as illustrated in the profile, are expected to prevail under Alternative #3 (self-certification) and Alternative #5 (provisional registration). Under Alternative #4, which allows no waivers, the barriers to entry would be increased particularly for the small volume market formulators. Under the current Agency regulations, there is a "horizontal" exemption clause which waives much of the registration requirements resulting in a very low registration cost. Formulators who incorporate a previously registered active ingredient into their own formulation are not held responsible for the testing required on the technical grade active ingredient nor are they required to share in the costs associated with the testing requirements for the active ingredient. As previously discussed for producers, the extent of product differentiation would remain high for the alternatives reviewed. However, under Alternative #4, the withdrawal of market volume on speciality products would somewhat decrease product differentiation.

D. Comparison of FIFRA Registration Compliance Costs

With regard to the pesticides regulatory program, industry incurs compliance costs for various laws and sections of those laws. A primary purpose of this report is to evaluate registrants', costs of complying with data requirements for registration under Section 3 of FIFRA (the Federal Insecticide, Fungicide and Rodenticide Act, as amended). Industry also incurs costs of complying with other sections of FIFRA and with some parts of FFDCA (the Federal Food, Drug and Cosmetic Act) and RCRA (the Resource Conservation and Recovery Act).

The industry, as affected by compliance costs, consists of registrants (basic producers and formulators) and others (pesticide users, custom applicators, dealers, distributors, and state agencies). The total cost of compliance with all sections of FIFRA, disposal requirements of RCRA and with the tolerance setting requirements of FFDCA is estimated to be in the range of $227 - $242 million annually for all sectors of the pesticide industry (Table VI-2). Approximately 70 percent of this amount is incurred in connection with basic production and formulation combined ($158 - $173 million), and 30 percent for other purposes ($69 million). The single industry category most affected by compliance costs is basic production. Its compliance costs are estimated to be in the range of $116 - $127 million annually, or about 52 percent of total compliance costs for the industry.

Figure VI-6

Market Structure Profile of U.S. Pesticide Formulators

Factor	Key Word Description	Explanation
1. Number of Firms		Approximately 3,300 formulators in the U.S.
2. Concentration		
a) Overall	moderately high	Moderately high and increasing somewhat at all levels. Four firms produce approximately 25% and 20 firms produce the bulk of total formulated pesticides.

	Concentration Rates (Percent of Production) 4 firms	 20 firms	 50 firms
b) Ag. Herbicides	53	67	68
c) Ag. Insecticides	46	83	93
d) Household and Industrial Pesticides	52	85	97

Factor	Key Word Description	Explanation
3. Product Differentiation	high	Each ingredient tends to be chemically distinct and unique efficacy, persistance and toxicity in crops and non-target organisms. Formulations of the same active ingredient differ only by the type of inert ingredients. Sellers differentiate by offering ancillary goods and services with products.
4. Barriers to Entry		
a) Economies of Scale	none	No major overall economies of scale
b) Capital Requirements	not capital intensive	Much less capital intensive than pesticide producers. The ratio of value added to gross book value of assets for formulators is the same as the ratio for all manufacturers as a whole, 1.30.
c) Research and Development	very little	There seems to be little R&D by formulators.
d) Integration	evident but low	Firms commonly operate in several site/classes of pesticides. Manufacturers sometimes formulate their own pesticides and/or have some of their production formulated by others under contract and sold under their own labels. An estimated 13-15% of pesticide production is retained by the manufacturer for formulation. In recent years manufacturers have begun to formulate more of their own products, but the industry does not have a high degree of vertical integration except through contractual arrangements between producers.

Figure VI-7

Competitive Behavior/Performance Profile of U.S. Pesticide Formulators

Factor	Key Word Description	Explanation
1. Pricing Patterns	difficult to analyze due to data limitations	The USDA index of prices paid by farmers (composite of 12 leading formulated pesticides) begins to rise a few years earlier than the OPP and ICF producer price indices and somewhat later than the BLC producer price index. In aggregate, the four indices show steady price declines during the 50's and 60's attributed to process improvements for recently developed products; and price increases in the 70's associated with inflationary conditions and petroleum prices. Other factors being equal, patented products have higher prices than non-patented products.
2. Non-Price Indicators		
a) Investments	increasing	Investment by pesticide formulators jumped in the mid-1970's following several years of relatively low levels of investment during the early 1970's. The pesticide industry has responded to excess demand with increased capacity relatively quickly, an indication of a competitive industry behavior.
b) Product Strategy and Advertising	extensive	Pesticide manufacturers make a considerable effort to advertise their products and create brand preference. The attempt to create brand preference extends to the smaller formulators and distributors, who typically sell pesticide products under private labels. Extension agents, farm organizations, magazines and word of mouth are also factors affecting user's pesticide-use decisions.
3. Research and Development		
a) Expenditures Trends	very little R&D done by formulators that do not produce active ingredients	There appears to be little R&D by pesticide formulators. Roughly 30 companies contribute the bulk of R&D expenditures and the majority are large multi-product companies which are manufacturers of active ingredients.

Table VI-2. Annual Industry Costs of Compliance with Pesticides Regulation under, RCRA, FIFRA, FFDCA a/, 1980 Estimates.

Law or FIFRA Section	Basic Production	Formulation	Combined B.P. and Formulation	Other	Total
	$ Million				
Data Costs					
3. Cost of Data for Registration b/					
25 Standards/yr.	53.4	24.0	77.4	—	77.4
40 Standards/yr.	63.8	28.6	92.4		92.4
FFDCA c/	35.0	—	35.0	—	35.0
6. HPAR Data	5.5	—	5.5	—	5.5
Other Costs					
3. Registration Activities d/	13.6	5.8	19.4	—	19.4
4. Restricted Use/Application Certification	—	—	—	33	33
6. Rebutting HPARs	2.1	NA	2.1	0.3	2.4
7. Registration of Establishments	0.5	2.6	3.1	—	3.1
8. Books and Records	1.5	6.7	8.2	—	8.2
9. Inspection	0.1	0.2	0.3	—	0.3
Disposal and Storage					
RCRA	4.5	0.8	5.3	22.6	27.9
FIFRA/Section 19	—	—	—	13.1	13.1
24. State Requirements	—	—	—	—	—
25. Child Resistant Packaging	Sm	Sm	1.7	—	1.7
TOTAL e/ ($ million)	116.2-126.6	40.1-44.7	158.0-173.0	69	227.0-262.0
FIFRA Data Costs f/ Percent of Total	46-50	60-64	49-53	—	34-38

Note: - indicates that industry category is not affected.
NA means no estimate available.
Sm indicates that no estimate is available, but impacts in industry is expeced to be quite small.

a/ Costs for registration data (25 standards/year and 40 standards/year) are mean costs for first ten years after implementation of guidelines; remainder of costs are estimates for 1980.

b/ Exclusive of R&D expenditure for HPARs.

c/ Costs of data for establishing tolerances in addition to those included in the FIFRA Section 3 figures above.

d/ Exclusive of costs of generating data. These costs have been evaluated separately and are displayed under "Data Costs" above. Included are "Administration/Overhead" costs for registration-related R&D, plus "Registration" costs (from NACA, 1980, Schedule 6-A). Basic production and formulation shares of these costs have been set proportional to their share of Section 3 data costs.

e/ Low end range from 25 standards/yr; high end for 40 standards/yr.

f/ Subtotal of Section 3 + HPAR data + FFDCA data.

The cost of studies for generating the data necessary for compliance is the major component of compliance costs. Depending on whether it is assumed that EPA will process 25 or 40 registration standards per year, registration data costs account for 49-53 percent of total compliance costs for registrants. Other members of the industry do not generally share in the costs of generating data. If data costs for tolerances (FFDCA compliance) and RPAR activities are included, the sum of all data costs accounts for approximately 80 percent of total compliance costs for registrants (Table VI-2).

Earlier in this report, several alternatives were described -- reference guidelines, regulatory requirements, self-certification, comprehensive data requirements, and provisional registration. Costs of compliance for registrants (basic producers and formulators) under each of the alternatives are compared in Table VI-3. The compliance cost totals fall into a range from approximately $150 - $210 million. Alternative #4 ($188 - $209 million) is at the upper end of the range and alternative #3 ($148 - $159 million) is at the lower end. The differences among these direct and indirect compliance costs for the alternatives were described in Section V of this report.

In the above discussion, only regulatory activity associated with the proposed registration requirements have been addressed. The Office of Pesticide Programs has also considered changes in two other areas: RPAR Risk Criteria, and Registration, Reregistration and Classification Procedures (40 CFR, Part 162; FIFRA Section 3 Regulations). Compliance costs under the current and proposed programs are displayed in Table VI-4 for each of the three regulatory proposals. They total $115 - $130 million annually for the current program, depending on whether 25 or 40 registration standards are processed annually. Under the proposed changes, total compliance costs would be reduced slightly to a range of $111 - $126 million annually. Under either the current or proposed programs, compliance costs associated with all of the proposed actions are about 50 percent of costs for the industry (Table VI-5). The proposed changes would lower total compliance costs to a degree, i.e., in the range of $3 - $4 million.

Table VI-3
Annual Registrant Compliance Costs with Pesticide Regulation under FIFRA, FFDCA and RCRA, by Alternative a/

Law or FIFRA Section	Alternatives				
	#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self Certification	#4 Comprehensive Data	#5 Provisional Registration
	$ Million				
3. Cost of Data for Registration b/					
25 Standards/Yr.	77.4	77.4	63.0	111.1	71.2
40 Standards/Yr.	92.4	92.4	74.2	132.0	86.2
FFDCA c/	35.0	35.0	35.0	35.0	35.0
6. RPAR Data	5.5	5.5	8.5	0.5	6.5
Other Costs					
3. Registration Activities d/	19.4	19.4	11.7	22.1	18.2
6. Rebutting RPARs	2.1	2.1	3.1	0.5	2.6
7. Registration of Establishments	3.1	3.1	3.1	3.1	3.1
8. Books and Records	8.2	8.2	8.2	8.2	8.2
9. Inspection	0.3	0.3	0.6 (0.3-0.9)	0.3	0.3
24. State Requirements	—	—	7.5 (5.0-10.0)	—	—
25. Child Resistant Packaging	1.7	1.7	1.7	1.7	1.7
RCRA/Disposal	5.3	5.3	5.3	5.3	5.3
TOTAL e/	158.0-173.0	158.0-173.0	147.7-158.9	187.8-208.7	152.1-161.8

Note: – indicates that alternative is not affected.

a/ FIFRA – Federal Insecticide, Fungicide and Rodenticide Act; FFDCA – Federal Food, Drug and Cosmetic Act; RCRA – Resource Conservation and Recovery Act. All costs in 1980 dollars.

b/ Costs for registration data (25 standards/yr. and 40 standards/yr. are mean costs for first ten years after implementation of guidelines.

c/ Costs of data for establishing tolerances in addition to those included in the FIFRA, Section 3 figures above.

d/ Exclusive of costs for generating data. These costs have been evaluated separately and are displayed under "Data Costs" above. Included are "Administrative/Overhead" costs for registration-related R&D, plus "Registration" costs (from NACA, 1980, Schedule 6-A).

e/ Low end of range for 25 standards/yr; high end of range for 40 standards/yr.

Table VI-4

Annual Compliance Costs of Proposed Actions for All Affected Parties; Under Current and Proposed Regulations by Regulatory Area

Regulatory Area	Current	Proposed	Difference
	($Million)		
Registration Data a/	109.0-124.0	109.0-124.0	0
RPAR Risk Criteria	7.9	7.1	-0.8
Section 3 Regulations	5.8	2.4	-3.4
Total b/	115.1-131.1	111.7-126.7	-3.4-4.4

a/ Lower end of range for 25 standards/yr.; upper end for 40 standards/yr.

b/ Total for current and proposed columns is not the sum of the columns. The RPAR activity is indirectly affected by Registration Guidelines and the $7.9 million RPAR compliance cost is included in the compliance cost figures for these guidelines. To avoid double-counting, this has been taken into account when calculating the totals.

Table VI-5

Compliance Costs of Proposed Actions Compared to Total Compliance Costs

Compliance Cost Category	Current	Proposed
	- - - - - - - - - - -$ Millions-	- - - - - - - - - -
Proposed Actions a/	115.1-131.1	111.7-126.7
Other FIFRA Section:		
4. Restricted Use/Applicator Certification	33	33
5. Experimental Use Permits b/	--	—
7. Registration of Establishments	3.1	3.1
8. Books and Records	8.2	8.2
19 Disposal and Storage	13.1	13.1
25. Child-Resistant Packaging d/	1.7	1.7
FFDCA	35.0	35.0
RCRA	27.9	27.9
Subtotal	122.0	122.0
TOTAL	237.1-252.1	233.7-248.7
Proposed Actions ÷ Total (percent)	49-52	48-51

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a/ From Table VI-4.

b/ Both data and administration costs are associated with experimental use permits. However, these costs are contained in the guidelines and Section 3 calculations under "Proposed Actions." To avoid double counting, this row item is deleted.

VII. PESTICIDE USER IMPACT ANALYSIS

A. Overview

The United States uses approximately 1.2 billion pounds of pesticides annually, at a user cost of about $5.8 billion (EPA, 1980). Manufacturers have registered more than 40,000 pesticide products containing 1,400 active ingredients. These pesticide products control about 21,500 pest species. All major economic sectors use pesticides in the United States (Table VII-1).

As discussed in Section V, the expected data requirements and indirect costs of providing the data required under the reference guidelines for registration are estimated to range from $84 to $134 million annually. However, as previously discussed, the industry is already complying with the majority of the requirements under Alternative #1 (and 2). Hence, the additional incremental costs associated with the alternatives which would impact users in the coming years are estimated by the cost differences between Alternative #1 and Alternatives #2, #3, #4, and #5. The costs associated with the Alternatives are shown in in Table VII-1.

The incremental costs of the Alternatives are estimated as follows:

	Costs ($ millions)		
Alternative	Absolute	Incremental	% of sales
Reference Guidelines	84-134	0	0
Regulatory Requirements	84-134	0	0
Self-Certification	64-138	-20 to 4	-0.3 to 0.1
Comprehensive Data Req.	104-177	20 to 43	0.3 - 0.7
Provisional Registration	79-127	- 7 to -5	-0.1

Therefore, the cost impacts on users would be a small amount with a range from minus 0.3 to plus 0.7 percent of pesticide costs, depending upon the operative scenario (see Section V).

B. Agricultural Users

The agricultural sector accounted for about 72 percent (846 million pounds a.i.) of pesticide use and about 62 percent ($3.6 million) of pesticide sales in the U.S. during 1980. A USDA survey in 1976 found that pesticides were applied to over 60 percent of the land used for major field crops and hay (Eichers, et al., 1978). For specific field crops such as peanuts, cotton, tobacco, corn, and soybeans, over 90 percent of the acreage received pesticide treatments.

Table VII-1 Summary Distribution of Pesticide Costs by Pesticide User Groups by Alternative

Pesticide User Group	Annual Pesticide Sales a/		Reference Guidelines		Regulatory Requirements		Self-Certification		Comprehensive Data Requirements		Provisional Registration	
	$	% of Total	Absolute Cost ($) b/	% of Sales	Absolute Costs ($) b/	Incremental Cost($)	Absolute Costs ($) b/	Incremental Costs ($)	Absolute Costs ($) b/	Incremental Costs ($)	Absolute Costs ($) b/	Incremental Costs ($)
	Mil.	%	Mil.	%	------------	------------	------------	------------ Millions	------------	------------	------------	------------
Agriculture	3,600	62	52-83	1.1-2.0	52-83	0	40-86	-12 to 3	64-110	12 to 27	49-79	-4 to -3
Industry, Commerce and Government	1,390	24	20-32	1.1-2.0	20-32	0	15-33	- 5 to 1	25-42	5 to 10	19-30	-2 to -1
Household	810	14	12-19	1.1-2.0	12-19	0	9-19	- 3 to 0	15-25	3 to 6	11-18	-1 to -1
Total	5,800	100	84-134	1.1-2.0	84-134	0	64-138	-20 to 4	104-177	20 to 43	79-127	-7 to -5

a/ Source: EPA, Pesticide Industry Sales and Usage: 1980 Market Estimates, Washington, D.C. September 1980.
b/ Source: Chapter V as previously presented.

Despite the relatively widespread use of pesticides in the agricultural sector, their costs accounted for only 3 percent of the 1976-1978 average farm production expenditures (derived from annual data in Agricultural Statistics, 1980). The most important expenditures of U.S. farmers for factor inputs are for feed, repair and operation of farm equipment, depreciation, and miscellaneous costs.

The extent of agricultural pesticide use varies by crop site and region. A comparison was made of current pesticide expenditures with the total variable costs for producing individual field crops, fruits, and vegetables. (In addition to pesticide costs, variable cost of production includes the costs for seed, fertilizer, field cultivation, and harvesting.)

The share of pesticide costs in the production budgets for cotton varies significantly by region. In the major cotton producing states of Texas, Mississippi, and California, pesticide costs range from 10 to 31 percent of the variable costs of production. For field crops such as peanuts, corn, and soybeans, pesticide expenditures in the major producing states range from about 15 to 28 percent of variable costs. Pesticide treatment costs in wheat account for only about 1 percent of variable costs. For fruit crops such as apples and oranges, pesticide costs are about 13 percent of variable costs. For vegetable crops such as carrots, broccoli, snapbeans, and tomatoes, 3 to 6 percent of the variable costs are for pesticide treatments.

Studies required for registration of agricultural pesticides under the Regulatory Requirements are expected to cost pesticide manufacturers and formulators an estimated $84 to $134 million per year. Under the simplifying assumptions that pesticide users will not reduce their consumption of pesticidal inputs (i.e., the demand curve is relatively inelastic), retail prices of agricultural pesticides would increase from a minus 0.3 to plus 0.7 percent for the alternative consideration. For the crops discussed above, the maximum increase in pesticide costs per acre would range from less than $.01 for wheat to less than $0.02 for tomatoes. The proposed alternative would not increase the variable production costs of these crops.

The small potential change in pesticide costs would have little noticeable effect on the costs or production of farm commodities. Likewise retail prices of food items should not be perceptively affected by the proposal to establish data requirements for registering pesticides. Overall, the incremental impact of the proposed Part 158 on the agricultural economy should not be significant.

C. Non-Agricultural Users

1. Profile of Non-Agricultural Users

This section provides a descriptive overview of the domestic uses of pesticides on industrial, commercial, institutional, household, and governmental sectors (ICF, 1980) and estimations of typical user cost impacts resulting from the regulatory requirements and alternative scenarios. In each example, the added costs to pesticide users (assuming all added costs resulting from the regulations are passed on from the manufacturer to the user) are shown to be negligible relative to the value of output.

a). Industrial

All types of pesticides, including rodenticides, miticides, and nematocides are used in industrial complexes. Industrial herbicides primarily control vegetation along roads, in parking lots and equipment yards, and around rights-of-way for railroads, pipe lines, and power lines.

Insecticides control pests such as termites, roaches, ants, and mosquitoes in forests, lumber yards, greenhouses, and nurseries. The food processing industry uses insecticides and rodenticides to control pests during production and storage operations.

Pesticides are also used in water quality management. Weeds, insects, algae, and fungi create problems in static water areas. Their control is of special importance in industrial processing waters and in cooling towers.

Control of the various pests is done by commercial pest control operators, lawn and tree services, or the industrial firm itself. When a firm does not employ the services of outsiders, it usually buys its pesticides from janitorial supply houses.

b). Commercial

Commerical firms have essentially the same types of pest problems as do industrial firms. They too must control unwanted vegetation, insects, vertebrates, and fungus problems. A wide variety of chemicals are used in this sector similar to the industrial sector.

c). Institutional

Use of pesticides by the institutional sector is small in comparison to the industrial and commercial sectors. Institutions include homes for the aged, blind, orphans, deaf and dumb, private grade schools, high schools, and colleges, churches, private hospitals, tax-exempt charitable foundations, museums, and other nonprofit organizations. Pest control is incidental to the normal functioning of the organization, and primarily involves landscaping and control of nuisance pests indoors.

Hospitals have very important pest control needs. Control of all insects, vertebrates, and fungus, as well as bacteria and virus, is essential to providing the healthy environment hospitals require.

d). Household

Residential pesticides are used for both indoor and outdoor purposes: herbicides control weeds in lawns and gardens; fungicides control growths on trees and shrubs; insecticides, miticides, and rodenticides protect structures and living area from infestation; and biocides are used as disinfectants for personal hygiene and in sanitizing surfaces.

e). Government

Government agencies at the federal, state, and local levels use pesticides for such purposes as disease control, road maintenance, land and water management, and rodent or other predator control.

2. Estimated Guideline Impacts to Selected Non-Agriculture Users

As discussed previously, industry, commerce, institutions, and government use herbicides to control unwanted vegetation, insecticides to control destructive insects, fungicides and wood preservatives to protect structures, and fumigants to control destructive pests and disease (EPA, 1974). Given the size and diversity of this group (i.e., non-agricultural users), an exhaustive evaluation would be far beyond the scope of the present analysis. Therefore, in this section, estimates of the cost impacts due to the alternative data requirements are estimated only for some major categories of non-agriculture users.

a). Wood Preservatives

The wood preservation industry in the United States has developed because of the need for prolonging the life of wooden structural members, primarily where contact with the ground is intended (EPA, 1974). Wood is preserved by the treatment(s) with a variety of chemicals which have fungicidal, insecticidal, and fire retardant properties. Historically, railroad ties, telephone poles, and marine pilings treated with creosote have been the major products of the industry. In recent years, lumber and plywood treated with leach-resistant preservative salts have experienced rapid growth.

The wood preservation industry provides the only major use for creosote (other than fuel) and consumes over a billion pounds of creosote annually. About 46 million pounds of pentachlorophenol—almost 80% of the total amount produced—is also consumed in the preservation of wood. Certain inorganic products containing chromium, copper, and arsenic are also used in relatively large quantities for the preservation of wood. The total amount of these products used in wood preservation amounts to about 41 million pounds, valued at about $190 million in 1978, representing only a small part of the annual billion dollar preserved wood market in the U.S. If the additional data required for the proposed alternatives were to cost from minus 0.3 to plus 0.7 percent of pesticide sales, and if those costs were to be absorbed uniformly by all the users, then the wood preservation industry would experience about a $570 thousand decrease to $1,330 thousand increase in pesticide costs, a very small part of the wood preservative market.

b). Railroads

Railroads are concerned with controlling vegetation along their rights-of-way. Vegetation control is mandatory on an 8 to 24-ft wide band centered over the rails. This control zone constitutes a firebreak to protect adjacent properties from sparks thrown off by the wheels of railroad cars. The faster the trains travel through an area, the wider is the required weed-free area. In addition, weeds shorten the life of railroad ties, can reduce traction for braking, reduce drainage, and foul the ballast on tracks.

There are approximately 330,000 miles of track in the United States. Three distinct areas on the track require weed control: the ballast, the roadbed, and the right-of-way. The ballast is a strip 12 to 16 ft wide, made of coarse material such as cinders or gravel, and is very porous. Insoluble and contact herbicides are the most suitable for use on the ballast. The roadbed and rights-of-way require soil sterilants to remove vegetation and provide the firebreak mentioned above.

Total acreage treated by the railroads with herbicides amounts to about 766 thousand acres, which includes the tracks, the yards, and the bridges and sidings. An estimated 11.5 million pounds of chemicals are used annually for this purpose by railroads in the U.S. (EPA, 1974). The peak consumption for all herbicides for railroads was estimated to be about $16 million per year (Kline, 1976B). If the additional data required under alternatives to the reference guidelines were to cost from a minus 0.3 to plus 0.7 percent of pesticide sales, and if these costs were distributed uniformly among all users, then the railroads would experience about a $48 thousand decrease to a $112 thousand increase over current annual pesticides expenditures representing a very small part of total railroad budgets.

c). Utilities

The utility companies are concerned with controlling vegetation along their rights-of-way. Utility rights-of-way include land areas devoted to the transmission of communications, electrical power, gas, and fluids such as oil, sewage, and water. Transmitting devices may be underground, laid on the soil, or suspended overhead on poles and towers. The land area involved is long and narrow—usually many miles long by 10 to 200 ft wide.

The total consumption of herbicides by electrical utilities is about 5 million pounds and was slightly over $15 million in 1975 (Kline, 1976B). If the additional data required under alternatives to the reference guidelines were to cost from minus 0.3 to plus 0.7 percent of pesticide sales, and if these costs were distributed uniformly among all users, the electric utilities would experience about a $45 thousand decrease to a $105 thousand increase over current annual pesticide expenditures, an insignficant percent of the total industry costs.

d). Professional Pesticide Applicator Services

(i) Pest Control Operators

Pest control operators (PCO's) are commercial firms that provide service for institutional, commercial, industrial, and residential clients. Both insect and vertebrate pests are controlled by PCO's using a wide variety of chemicals. Most of their work is done indoors. For expository purposes, PCO's are divided into two major categories--structurcal PCO's (exterminating, wood-destroying organisms) and general PCO's. Approximately 8,000 individual firms exist throughout the U.S.; about half of them are one or two-person operations. The two-person companies are by far the most numerous, each having many firms located across the country.

The total dollar volume of the PCO industry in 1975 is estimated at about $900 million, of which $53 million represents the cost of the pesticides employed. If the additional data required for the alternatives to the reference guidelines were to cost from minus 0.3 to plus 0.7 percent of pesticide sales, and if these costs were distributed uniformly among all users, the PCO would experience about a $159 thousand decrease to a $371 thousand increase over current annual pesticide expenditures, representing an impact of less than 0.1% of total dollar PCO industry market.

(ii) Lawn and Tree Services

Pest control firms that provide lawn service and tree care are a separate group from PCOs (although many firms providing diverse services would fall under both categories). There are an estimated 15,000 individual firms providing lawn and tree care in the U.S.

Companies providing landscaping and lawn services consume about $37 million in insecticides, herbicides and fungicides (Kline, 1976B). If the additional data required for registration were to cost from minus 0.3 to plus 0.7 percent of pesticide sales, and if these costs were distributed uniformly among all users, the lawn and tree service industry would sustain an $111 thousand decrease to a $259 thousand increase over current annual pesticide expenditures.

e). Textiles

The U.S. textile industry with total sales of about $35 billion in 1978 used about $3 million in bactericides, mildewicides and other preservatives, with a projected annual increase of about 3% through 1983. If the additional data required for alternatives to the reference guidelines were to cost from minus 0.3 to plus 0.7 percent of pesticide sales, and if these costs were distributed uniformly among all users, the textile industry would experience about a $9 thousand decrease to a $21 thousand increase over current annual pesticide expenditures, representing an insignificant part of total textile sales in the U.S.

f). Paint

In 1978 paint sales reached almost $5 billion (Kline, 1976B) (in producer prices), consuming about 15 million pounds of biocides valued at somewhat less than $35 million. If the additional data required for alternatives to the reference guidelines were to cost from minus 0.3 to plus 0.7 percent of pesticide sales, and if these costs were distributed uniformly among all users, the paint industry would experience about a $115 thousand decrease to a $240 thousand increase over current annual pesticide expenditures, representing an insignificant part of the total paint sales.

g). Commercial Forests

Of an approximate 483 million acres of commercial forest land, only a small percentage is treated with pesticides. Estimated annual manufacturers' sales of pesticides between 1975 and 1980 is about $10 million annually (Kline, 1976B). If the additional data required for alternatives to the reference guidelines were to cost from minus 0.3 to plus 0.7 percent of pesticide sales, and if these costs were distributed uniformly among all users, the commercial forests would experience about a $30 thousand decrease to $70 thousand increase over current annual pesticide expenditures.

D. Summary of User Impacts

The aggregate change in the cost of pesticides due to the various alternatives to the reference guidelines would range from a decrease of $20 million to as much as an increase of $43 million representing a minus 0.3 to plus 0.7 percent, depending which alternative is enacted (Table VII-1). The bulk of such impacts would be sustained by agricultural users, where pesticides constitute a significant share of factor inputs. In contrast, in the non-agricultural sector, pesticides constitute only a minute fraction of total inputs. One notable exception is the wood preservation industry, wherein pesticides constitute nearly 16 percent of total inputs (U.S. Dept. of Commerce, 1972).

VIII. WELFARE IMPACT ANALYSIS

As shown in Section VII, alternative data requirements would affect pesticide production costs. Further, it was assumed that the incidence of these changes would be borne ultimately by pesticide users. Economic theory predicts that such users, when faced with an increase in the cost of a factor of production (pesticides, in this instance) will reduce their demand for that input, either by substituting other inputs or by reducing output. Thus, depending upon the technical possibilities for factor substitution, as well as the relative prices of the alternative inputs, prices of consumer goods may be increased depending upon which of the approaches is selected for data requirements.

In the two cases where costs decrease, it cannot be stated *a priori* that in the short run agricultural producers would increase their usage of pesticides in response to lower prices. If the current level of usage is optimal in a technical sense, the agricultural producers would have no incentive to increase pesticide inputs in response to lower prices. In this event, the reduced pesticide costs would result in higher profits for producers. In the long run, these incremental profits would be progressively eliminated as growers expanded their output (in response to the incentive of greater net returns). Thus, agricultural output would expand as a result of lower pesticide prices; and consumers would ultimately benefit from the resulting lower prices.

If the current level of pesticide usage is not technically optimal, then demand for pesticides would increase in the short run; and as a result, agricultural output (through yield enhancement) would increase. Again, consumers would ultimately benefit from the resulting lower prices.

Although it has some theoretical limitations as a measure of economic worth, the use of the net welfare concept to measure the efficiency 1/ impact of a given regulation has become standard practice 2/. Thus, the change in welfare resulting from changes in data requirements can be measured by the algebraic sum of the change in consumers' and producers' surplus. An attempt at an empirical estimation of this impact is made in the following parts of this report section.

1/ The efficiency solution includes only those effects which can be measured in the market. Thus excluded are all phenomena variously characterized as negative externalities, environmental spillovers, etc. Equity considerations are also excluded.

2/ For a discussion of both the theory as well as the controversy surrounding this concept, the reader is referred to: Hertford, Reed, and Andrew Schmitz, "Measuring Economic Returns to Agricultural Research," in Arndt, Thomas M., Dana G. Dalrymple, and Vernon W. Ruttan (eds.) *Resource Allocation and Productivity in National and International Agricultural Research.* Minneapolis: University of Minnesota Press, 1977.

A. Agricultural Sector

In order to estimate the net welfare change resulting from the proposed data requirements, the hypothesized pesticide cost changes were exogenously inserted (as changes in the production costs of agricultural producers) into a simulation model 1/ of the field crops portion of the agricultural economy. The crops included in AGSIM account for approximately 67% (USDA, 1981) of total agricultural sales.2/ The resulting changes in net welfare ranged from a loss of \$12.2 million per year to a gain of \$5.4 per year, depending upon which scenario was assumed operative (Table VIII-1).

With regard to the remainder of the agricultural economy---i.e., for crops other than those modeled in AGSIM---only some crude guesses can be made as to the magnitude of the net welfare changes due to increased pesticide costs. By extrapolating from the results in AGSIM for the major field crops, one can derive at least an upper bound for the estimated net welfare impact for these other crops. The results of this procedure are also shown in Table VIII-1. Analogously to the previous results, the estimated annual impacts for the other crops for all alternatives taken together range from a loss of \$6.0 million to a gain of \$5.4 million.

The validity of the foregoing estimates for non-AGSIM crops can be corroborated only indirectly from a set of relationships found in the 1972 Input-Output Tables (U.S. Department of Commerce, 1979). When the value of pesticide inputs for all other crops not included in AGSIM (specifically: grass seeds, tobacco, fruit, tree nuts, vegetables, sugar crops, and miscellaneous) is divided by the total value of pesticide inputs for all crops, the resulting ratio 1 : 5.27 or about 19 percent.3/ From Section VII of this report, it can be seen that the maximum annual increase in pesticide costs for agricultural users would be \$27 million (\$110 million - \$83 million; see Table VII-1). Assuming that a constant ratio of pesticide use between the two crop groupings (i.e., AGSIM vs. non-AGSIM crops) still holds, the maximum cost increase under any scenario for non-AGSIM crops would be \$5.1 million (\$27 million * .19 = \$5.1 million) ... a value which is close to the maximum net welfare impact for non-AGSIM crops of \$6.0 million (see Table VIII-1).

1/ Reference here is to AGSIM, an econometrically based simulation model developed by C. Robert Taylor and Glenn Collins at Texas A&M University under EPA Contract No. 68-01-5041.

2/ The following crops are modeled in AGSIM: corn, cotton, wheat, barley, oats, sorghum, and soybeans.

3/ Derivation: 148.7/535.2 = 0.1897. The pesticide input values, expressed in millions of 1972 constant dollars, were taken from row 27.03 of Table 1, Volume I of the 1972 Input-Output Tables. The numerator is the sum of the following column entries: 2.0203, 2.0300, 2.0401, 2.0501, 2.0502, and 2.0503. The denominator is the sum of the following entries: 2.0100, 2.0201, 2.0202, and 2.0600.

Table VIII-1. Estimated Annual Change in Net Welfare Due to Costs of Alternative Data Requirement Approaches for the Agricultural Sector

Alternative	Annual Net Welfare Change a/		
	Field Crops b/	Other Crops c/	All Crops d/
	- - - - - - - - - - - - - -$ Millions- -	- - - - - - - - - - - -	
Reference Guidelines	0	0	0
Regulatory Requirements	0	0	0
Self-Certification	+5.44 to -1.15	+2.68 to -0.57	+8.12 to -1.72
Comprehensive Data Req.	-5.92 to -12.19	-2.92 to -6.00	-8.84 to -18.19
Provisional Registration	+1.15 to +1.98	+0.57 to +0.98	+1.72 to +2.96

a/ A positive sign indicates an increase in total economic welfare; a negative sign represents a decrease in total economic welfare.

b/ Results from AGSIM.

c/ [Net welfare change all crops] minus [net welfare field crops].

d/ Extrapolated by dividing AGSIM results by the percentage of total agricultural receipts represented by field crops. Example: \$-1.15 million/.67 = \$-1.72 million.

Thus the estimated net welfare impact for all agricultural commodities for the alternatives taken together would range from a loss of $18.2 million to a gain of $8.1 million annually. In view of the fact that personal consumption expenditures for food, beverages, and natural-fiber clothing in 1980 were roughly $400 billion (George and King, 1971) 1/, it is unlikely that impacts of these magnitudes (whether gains or losses) would be perceptible at the national level.

B. Non-Agricultural Sector

Unfortunately, no model which can measure welfare impacts in a manner analogous to AGSIM exists for the non-agricultural portion of the economy. While there is not sufficient data available to permit any rigorous analysis, fragmentary evidence from the economics literature suggests that the incidence of the cost increases due to any of the proposed data requirements options would fall (a) on the pesticide manufacturers, (b) on the pesticide users in the non-agricultural sector, or (c) be shared by both.

In a study of price behavior by stage of processing, Popkin (1974) has shown that retail prices in the non-food sector are generally less sensitive to changes in the prices of raw materials than are those in the non-food sector. Elsewhere it was shown that producers' prices in the food sector translate into retail price changes of equal magnitude or less (USDA, 1982). Taken together, these two points indicate that, at least in the short term, retail prices would most likely increase very little or not at all as a result of the proposed data requirements.

With regard to long-term effects, one might argue that the cost increases borne by the pesticide manufacturers and/or users might induce shifts out of the affected industries, ultimately resulting in higher consumer prices. As discussed previously in Section VII, however, pesticide expenditures account for only a small percentage either of total inputs or sales volume. Therefore, no perceptible long-term price effects would be expected.

C. Aggregate Welfare Impacts

The aggregate annual change in net welfare due to the imposition of data requirements would range from a loss of $34 million to a gain of $16 million per year. (excluding pesticide program costs and costs of adverse health-environmental effects). Whereas a substantial portion of the increased pesticide costs would be passed on to final consumers in the agricultural sector, in the non-agricultural sector,

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1/ Specifically, it was shown (Table 10, p. 62) that the elasticity of price transmission for a variety of foods was less than 1.0. The elasticity of price transmission for the the commodity is defined as follows: $\frac{\partial p^{retail}}{\partial p^{producer}} \cdot \frac{\partial p^{producer}}{\partial p^{retail}}$

most of the increased costs would be absorbed either by the pesticide manufacturers or the users of pesticides in the production of other goods and services for sale to final consumers. The breakout of net welfare changes by sector by alternative is shown in Table VIII-2.

D. Net Societal Benefits from Pesticide Use: An Alternative Approach

Given that the objective of the present analysis is to evaluate the economic impact of alternative regulatory approaches, it follows that the costs and benefits of the data requirements themselves have been the focus of this analysis. As an alternative approach, however, one might evaluate the costs and benefits of pesticide use rather than pesticide regulation(s). Indeed this alternative approach is implicit in the legislation which authorizes EPA to regulate the manufacture, sale, and use of pesticides. Thus, prior to the publication of any proposed regulation in the Federal Register, FIFRA requires the EPA Administrator to take into account: "...the effect of the regulation of production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy...".

While over the past several years the Economic Analysis Branch (EAB) within the Office of Pesticides has routinely incorporated the aforementoned factors into its RPAR-related pesticide "benefits analyses," such studies have been conducted on a chemical-by-chemical basis. Thus to date, agricultural economists have not succeeded in measuring aggregate net benefits of pesticide use in a rigorous manner The classic attempt was made several years ago by (Headley, 1968) whereby an aggregate production function for agriculture was estimated with pesticide expenditures included as an argument. By that author's admission, various data problems as well as serious collinearity between the variables left the empirical relevance of the estimated productivity parameters open to question.

In subsequent work, Headley limited himself to a qualitative or conceptual discussion of the benefits from pesticide use (Headley, 1972). Noting that economists typically dichotomize a given technological development as being either "output-increasing" or as "cost-saving," Headley nevertheless states that pest control activity in conjunction with other technological advances has resulted in both increased output and reduced costs. The key words here are "in conjunction with." While non-technical reports on agriculture routinely attribute significant yield increases to pesticides, it is interesting to note in Headley's estimated production function that the use of pesticides was highly correlated with both total labor ($r = 0.77$) and fertilizer ($r = 0.50$).

Table VIII-2. Estimated Annual Changes in Net Welfare by Sector Due to Costs of Alternative Data Requirements Approaches

Alternative	Annual Net Welfare Impacts by Sector a/		
	Agricultural b/	Non-agricultural c/	Total
	$ Millions		
Reference Guidelines	0	0	0
Regulatory Requirements	0	0	0
Self-Certification	+8 to -2	+8 to -1	+16 to -3
Comprehensive Data	-9 to -18	-8 to -16	-17 to -34
Provisional Registration	+2 to +3	+3 to +2	+5

a/ A positive sign indicates an increase in total economic welfare; a negative represents a decrease in total economic welfare.

b/ From Table VIII-1.

c/ Derived from data in Table VII-1.

In view of the foregoing considerations, one cannot state unambiguously that pesticide use results in increased output in the long run. In the short run, pesticides indirectly increase output by protecting the crop from pest damage, and hence increase output over and above what it would have been had pesticides not been used. This latter point assumes that pest control technology is fixed; but in the long run, however, producers will shift to the least-cost control techniques, which may or may not involve the use of pesticides. Viewed from this latter perspective, pesticide use is primarily a cost-reducing technology.

Since the regulatory process must take into account (and often focuses exclusively on) the short run effects of a given policy option, a measure of the benefits from pesticides in the short run is essential. As discussed previously, these short run benefits are most accurately viewed as (indirectly) output-increasing in nature.

To measure the short run benefits of pesticide use, one must answer the following question posed by Pimental et al. (1978): "What would our crop losses to pests be if all pesticides were withdrawn from use, and readily available non-chemical control methods were substituted where possible?" In answer to his own question, Pimentel estimated that the present crop losses with pesticides would increase from 33 percent of the total value of crop production to 42 percent following the ban of all pesticides.

In Table VIII-3, Pimentel's estimates of crop losses and additional costs imposed by a ban of all pesticides have been summarized and subsequently inflated to reflect 1980 price levels. This total ($11.1 billion) when divided by the total treatment cost with pesticides ($3.1 billion) yields a return of about $3.60 for each dollar spent on pesticide treatments.

Table VIII-3. Estimated Costs with and without Pesticide Use

Cost Item Description	Value (Billions of 1980 $)
Increased Crop Losses w/o Pesticides	6.4
Increased Costs of Non-Chemical Control Methods	4.7
Total	11.1 a/
Current Pesticide Treatment Costs (includes material and application)	3.1 b/

a/ Derived from Pimentel, 1978 updated to 1980 dollars.
b/ Derivation: $2.2 billion inflated by PPI factor of 1.39.

At $3.60, the return per dollar of pesticide expenditure estimated here is $.40 less than in the original work by Pimentel. This reduction has occurred because the value of agricultural production (the numerator) has increased more slowly than the cost of pesticide treatments (the denominator). Thus the benefit from pesticide use is not a fixed parameter, but instead a variable which fluctuates with (among others) agricultural prices.

To arrive at an estimate of net social benefits, all external public costs from pesticide use (e.g., deleterious health affects), must be added to the aggregte private costs (i.e., $3.1 billion; see Table VIII-2) of pesticide treatments. When Pimentel's estimate (Pimentel, 1978) for external public costs of $3 billion 1/ (annually) is inflated to 1980 dollars (i.e., $3 billion x 1.39) and added to aggregate private costs, the total cost of pesticide use is $7.3 billion annually ($3.1 + ($3.0 *1.39) = $7.3 billion). Use of the latter figure reduces the return per dollar of expenditure from about $3.60 to about $1.50 ($11.1 billion ÷ $7.3 billion = 1.52). The measure could just as well be interpreted as the more familiar benefit-cost ratio (BCR).

Conceptually it would be possible to evaluate the impact of the proposed regulatory requirements (and alternatives thereto) within the foregoing framework by adding the additional costs imposed by the guidelines to the denominator of the BCR. At the same time, the reduced social costs as a result of the implementation of the guidelines would be subtracted from the denominator. In the absence of any information with regard to the latter, it is not possible to predict the resulting change in the BCR.

Finally, it should be pointed out that the magnitude of the BCR shown above cannot be compared with any BCR's associated with the costs and benefits of pesticide regulations. Neither analytical framework is superior; the choice of which to use will obviously depend upon the focus of the analyst.

1/ By Pimental's own admission, this estimate is somewhat conjectural.

IX. OVERALL BENEFIT/COST ANALYSIS

A. Introduction

Executive Order 12291, issued February 17, 1981, directs Agencies initiating major rulemaking activities to conduct a regulatory impact analysis and submit it to OMB prior to publication of the proposed rules. Basically, the Executive Order calls for the Agency to calculate the costs and benefits of the proposed regulation and to make a comparison of them with the costs and benefits of other approaches. The proposed approach should be the one which maximizes net social benefits. The purpose of this section of the report is to integrate the results of the impact analyses reported in earlier sections into a benefit/cost framework and to report the results of the overall analysis as required by the Executive Order.

This analysis is conducted pursuant to EPA's interim guidance on conducting regulatory impact analyses (late November 1981 version) as well as the interim OMB guidance (June 1981 version) and the Executive Order itself. The analysis follows format and analytical framework guidance to the extent feasible at this time. The EPA guidance does recognize that the comprehensive framework called for under Executive Order 12291 is not completely achievable at this time, but that programs should work towards the goal of being fully responsive to the guidance in the longer term.

In the foregoing sections containing the impact analyses, estimates were made of benefit and cost outcomes of the five alternative pesticide regulatory approaches. In this section of the report, the results of those analyses are summarized in matrix form. Numerical or quantitative estimates of outcomes are presented where available. The results in other instances are summarized with the use of keywords or phrases reflecting the results of the analyses.

The results of the analyses are highly impacted by outcomes of a qualitative nature. Relatively few factors were capable of being fully quantified and/or monetized as is suggested by Executive Order 12291 and OMB/EPA Guidance. This makes it impossible to estimate "net benefits" directly as one would do if outcomes could be fully quantified and monetized, utilizing the standard cost/benefit framework. In order to bring the results of the analysis into "net benefit terms", a "cost/benefit rating technique" was developed for application to the analysis.

The cost-benefit analysis rating technique may be summarized as follows:

1. A total of 100 points is allocated to benefit factors.
2. A total of 100 points is allocated to cost factors.
3. The points within the benefit and cost areas are allocated to the various benefit and cost factors in proportion to the importance attached to the items by the management of the program. The more important the cost or benefit factor, the more points it receives and vice versa.

4. The points for each factor are allocated to the regulatory options in accordance with the quantitative and/or qualitative outcomes of the impact analyses as reported in earlier sections of the report.

5. The points allocated to each of the alternatives in each row are assigned independently from row to row with respect to benefits and costs.

6. The benefit ratings and the cost ratings are totalled giving an overall benefit rating and cost rating for each alternative. These ratings in turn are substracted to give a net benefit rating and are divided to give a benefit/cost rating ratio.

7. Intuitively, the alternative having the highest net benefit rating or highest cost/benefit rating ratio would be the preferred alternative and vice versa.

This framework is not to be confused with a true cost/benefit analysis. However, it seems to be a reasonable method of summarizing the various quantitative and qualitative benefit and cost factors and in arriving at an overall conclusion as to benefits and costs, taking into account the relative importance of various factors or criteria to the management of the program.

A key point, is that the assignment of 100 points to benefits and 100 points to costs, is done only for the sake of convenience in performing a comparative analysis of the alternatives with respect to benefits and costs. It is not to imply that benefits exactly equal costs on the average for the five options. Neither do the net benefit ratings nor the benefit/cost rating ratios of the individual alternatives necessarily reflect the true parameters which would obtain if the true benefit and cost values were known. However, these indicators are useful for purposes of comparing the relative merit of the alternatives, taking into account cost and benefit factors.

B. Costs

The results of the various cost analyses from the impact studies discussed earlier in this report are summarized in Table IX-1. For the five alternative approaches, program costs are taken directly from the earlier analyses, as are industry compliance costs, impacts on pesticide users and impacts on agricultural commodities and food prices. Estimates of dollar impacts were generated for each of these cost factors. In addition, impacts on the pesticide industry, including small firms, losses of pesticide products by users and other economic effects are also summarized in Table IX-1. These cost impacts are reduced to numerical ratings in Table IX-2 where the 100 points allocated to costs are distributed among the alternatives and the various cost factors. In that table, program costs are the highest ranking row item with 35 points, followed by industry costs of 30 points and by other long-term impacts on the pesticide industry, including small firms which received 20 points. In the ratings, pesticide user costs in dollar terms are afforded no points because this would amount to double counting of industry compliance costs (which are assumed to be passed on to users as add-ons to their costs of using pesticides).

Table IX-1

Summary of Costs of Alternative Approaches for Generating Hazard Testing Information on Pesticide Products

	#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self-Certification by Registrants	#4 Comprehensive Requirements	#5 Provisional Registration
Program Costs ($ million/Yr.)	$62.1	$58.0	$61.8	$62.2	$65.5
Industry Costs					
Direct and Indirect Compliance ($ Million/Yr.)	84-134	84-134	64-138	104-177	79-127
Other/Long-Term					
a. Producer Structure	medium to high concentration/ entry barriers	medium to high concentration/ entry barriers increased slightly	medium concentration/ entry barriers	high concentration/ entry barriers	medium concentration/ reduced entry barriers
b. Producer Competititve Behavior	oligopolistic, with occasional rivalry, especially during periods of declining demand	oligopolistic, with some proprietary products dominating markets	oligopolistic, but with increased competitive rivalry especially on non-patented products	oligopolistic, with powerful firms dominating competitive interaction	oligopolistic, with some increased rivalry of new products with old ones
c. Producer Performance	medium to high profits, R&D and product choice	medium to high profits and R&D; some loss in product choice possible	medium profits; R&D would suffer; product quality could suffer. Reduced time for registration.	very high profits; reduced product choices with abandonment of small value products	Medium to high profits; R&D incentives improved for new active ingredients due to earlier commercialization
d. Small Firm/Impacts	moderate cost impacts, except where waivers are disallowed	moderate cost impacts, except where waivers are disallowed	minimum impacts	major impacts due to no waivers	moderate cost impacts, except where waivers are disallowed

Table IX-1—continued

Summary of the Costs of Regulatory Guidelines and Alternative Approaches for Generating Information on Pesticide Products

	#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self-Certification by Registrants	#4 Comprehensive Requirements	#5 Provisional Registration
Pesticide User Costs ($ Million Annually)					
a. Non-Ag Users (38%)	32 - 51	32 - 51	24 - 52	40 - 67	30 - 48
b. Ag. Users (62%)	52 - 83	52 - 83	40 - 86	64 - 110	49 - 79
c. Loss of A.I.'s/Products	Few	Relatively low	Very few	Many	Few
Macroeconomic Impacts					
Ag Commodities/ Net Welfare Effects	Slight-Moderate	Slight-Moderate	Slight	Moderate	Slight
Other prices	-No significant effects-				
Employment	-No siginifcant effects-				

Table IX-2

Cost Ratings of Alternative Approaches for Generating Hazard Testing Information on Pesticide Products

	#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self-Certification by Registrants	#4 Comprehensive Requirements	#5 Provisional Registration	Total Rating Points
Programs ($ Million/Yr.)	7	6.5	7	7	7.5	35
Industry Costs						
Compliance ($ Million/Yr.)	5.9	5.9	5.0	8.5	4.7	30
Other/Long-Term						
a. Producer Structure	1.0	1.3	0.4	1.6	0.7	5
b. Producer Competitive Behavior	1.0	1.3	0.4	1.6	0.7	5
c. Producer Performance	1.0	0.7	1.3	1.6	0.4	5
d. Small Firms/Impacts	1.3	1.0	0.3	1.7	0.7	5
Pesticide User Costs ($ Millions Annually)						
a. Non-Ag Users (30%)	-	-	-	-	-	0
b. Ag. Users (62%)	-	-	-	-	-	0
c. Loss of Products	0.7	1.3	0.4	1.6	1.0	5
Ag. Commodities/ Net Welfare Effects	2.6	2.0	0.8	3.2	1.4	10
Other prices	-	-	-	-	-	0
Employment	-	-	-	-	-	0
Total	20.5	20	15.6	26.8	17.1	100

Option #4, Comprehensive Requirements, has the highest cost rating of 26.8 points followed rather closely by reference and regulatory requirements with about 20 points each. Self-certification received the lowest point rating of 15.6 points and provisional registration received a somewhat higher rating of 17.1 points. The key factor affecting the cost ratings was the cost of industry compliance, particularly with respect to comprehensive data requirements.

C. Benefits

The key word summary of benefits is presented in Table IX-3. Benefits are summarized in the terms of pesticide program benefits related to the long term certainty of registerability of pesticide products, time to obtain registrations, coordination problems, reduction in human health effects and reduction in environmental effects.

Generally, the options each affected the various benefit row items in the table. The only factor that was not particularly sensitive to shifting regulatory options was that of acute human hazards. Generally, program benefits increased with shifts from reference guidelines to regulatory requirements to comprehensive requirements. Benefits from provisional registration were in about the same range as for reference guidelines. Lowest benefits tended to be from self-certification by registrants, as certainty of registerability of products declined, coordination problems would emerge, (particularly between state and federal agencies), chronic health hazards increased and environmental hazards increased. On the other hand, self-certification would significantly improve program benefits in the area of reduced time to obtain pesticide registrations. This would benefit both producers and users of pesticides.

Significant program benefits are generated by the current program, generally operating as specified under the reference guideline option. Benefits are particularly important in the areas of human hazard reduction and environmental effects reductions from the use of pesticides. Significant benefits also are generated in the area of reduced acute human hazards even though each of the regulatory options is capable of generating about the same amount of benefits in that area.

The numerical ratings of the benefit factors for the five options are presented in Table IX-4. The most important program benefit area is that of reducing chronic human hazards which was accorded 50 of the 100 points allocated to benefits. Each of the other areas of benefits was assigned 10 points. The option receiving the lowest benefits rating was self-certification with 10 points followed by provisional registration and reference guidelines which each had about 20 points. Comprehensive data requirements and regulatory requirements had the highest benefit ratings of about 25 points. Thus, in terms of the benefits ratings, there are essentially three groupings as indicated by these point spreads.

Table IX-3

Summary of Benefits of Alternative Approaches for Generating Hazard Testing Information on Pesticide Products

	#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self-Certification by Registrants	#4 Comprehensive Requirements	#5 Provisional Registration
Pesticide Program Benefits					
a. Certainty of Long-Term Registerability of Products	Occasional problem chemicals obtain registrations; need to be withdrawn from market	Few problem chemicals registered	Many problem chemicals registered potentially	Very seldom would problem chemicals be registered	Few problem chemicals registered; sometimes chemicals would need to be removed after completion of data bases.
b. Time to Obtain Registration for New AI	85-95 months from chemical discovery	80-90 months	60-80 months due to less time required to review data within EPA and less testing time	100-120 months	60-80 months
c. Coordination with Other Programs	Occasional problems	Few problems	Very severe problems State/Federal relations.	Major problems - States want exemptions.	Moderate problems.
Health Effects					
a. Acute Human Hazards	52 deaths 2,800 hospitalizations.	52 deaths 2,800 hospitalizations.	Possible increase over other options	52 deaths 2,800 hospitalizations	52 deaths 2,800 hospitalizations
b. Chronic Human Hazards (Relative Order for Cancer/Oncognicity Cases Avoided)	3	2	5	1	4
-Other Effects -(Genetic, Reprod., Terata, etc.)	Some problems	Few problems	More frequent problems, including major ones	Infrequent problems	Some problems, including a few short term
Environmental Effects	Occasional unacceptable problems	Infrequent problems	Frequent problems, including some major impacts	Infrequent problems	Some problems, including a few short term

Table IX-4

Benefit Ratings and Cost/Benefit Rating Comparison for Regulatory Guidelines and Alternative Approaches Generating Information on Pesticide Products

	#1 Reference Guidelines	#2 Regulatory Requirements	#3 Self-Certification by Registrants	#4 Comprehensive Requirements	#5 Provisional Registration	Total Rating Points
Pecticide Program Benefits						
a. Certainty of Register-ability of Products	2	3	0	4	1	10
b. Time to Obtain Registration	1	2	4	0	3	10
c. Coordination with Other Programs	3	3.5	0	1	2.5	10
Health Effects						
a. Acute Human Hazard	2	2	2	2	2	10
b. Chronic Human Hazard	11	11	4	15	9	50
Environmental Effects	2.3	2.7	0	3	2	10
Total Benefit Rating	21.3	24.2	10	25	19.5	100
Total Cost Rating	20.5	20	15.6	26.8	17.1	100
Net Benefit Rating	0.8	4.2	- 5.6	- 1.8	2.4	-
Benefit/Cost Rating Ratio	1.04	1.21	0.64	0.93	1.14	1.00

D. Benefit/Cost Evaluation

Computations of the net benefit ratings and the benefit/cost rating ratios are presented in Table IX-4 along with the benefit ratings. The net benefits ratings are negative for two of the options (-5.6 for self-certification and -1.8 for comprehensive requirements). Provisional registration had a positive net benefit rating of 2.4 and regulatory requirements had the highest net benefit rating of 4.2 points. Reference guidelines had a small net benefit rating of 0.8 points. The net benefits ratings are particularly significant for regulatory requirements and self-certification, suggesting that these alternatives are considerably better and worse respectively, than the alternatives.

Possibly a more important or meaningful comparison is among the benefit/cost rating ratios which vary much more significantly across the alternative approaches. For example, the regulatory requirements ratio is 1.21, nearly twice that of self-certification by registrants. The reference guidelines option is slightly above 1.0 and the comprehensive requirement option is slightly below 1.0. Provisional registration is a close second to regulatory requirements with a 1.14 benefit/cost rating ratio.

The benefit/cost rating ratio, of course, does not represent a true benefit/cost ratio for the alternatives. However, it is an indication of the relative merit of the five options considering cost and benefit factors. Quite clearly regulatory requirements and provisional registration are the preferred alternatives taking into account both benefit and cost factors. Similarly, the self-certification alternative is the worst choice and the other two options of reference guidelines and comprehensive requirements are in the mid-range of overall desirability in terms of benefit and cost considerations.

E. Benefit/Cost Sensitivity

The benefit/cost rating ratios are dependent on subjective weightings assigned to the various categories of costs and benefits analyzed in this paper. Given the outcome is based on subjective measures, a sensitivity analysis using different weightening assumptions was prepared. Appendix 2 contains a summary of the sensitivity analysis. Three different sets of assumptions were made for both cost effects and benefit effects. For costs, emphasis was varied on program costs, industry costs, and a middle-of-the-road assumption. For benefits, emphasis was varied on environmental effects, health effects, and a middle-of-the-road approach. In each case, the middle-of-the-road option is the same as the ratings presented on costs and benefits in tables IX-2 and IX-4 respectively. The emphasis changes are reflected by changing the weights assigned to the effects categories. In all nine sets of ratios from Appendix 2, the preferred alternative approach was #2, regulatory requirements. The order of the other approaches varied only slightly as the interested reader can see in Appendix 2. The weighting factors used in this sensitivity analysis are also presented in Appendix 2.

F. Cost/Effectiveness

Absent a formal benefit/cost comparison, a cost/effectiveness analysis might be considered. Unfortunately the lack of quantifiable data on health and environmental effects from pesticides which limits the benefit/cost analysis prevents a formal cost/effectiveness evaluation also. Some information is available that do allow for some evaluation of relative effectiveness of the alternative approaches in achieving protection of health and the environment. Appendix 3 contains a discussion of this material.

X. SUMMARY OF IMPACTS ON SMALL BUSINESSES OR OTHER UNITS

The purpose of this section is to summarize and highlight the economic impacts on small businesses or other units. The profile and impact analysis for units of all sizes were presented in earlier sections of this report while only small business impacts are summarized in this section. Focus is upon pesticide registrants (primarily producers and formulators), governmental units and pesticide users.

The available EPA statistical data on registrants does not differentiate well between the various components of the pesticide industry, e.g., producers and formulators. However, EPA has gathered some Dun and Bradstreet data on registrants to facilitate disaggregated analysis of the producers and formulators.

A. Pesticide Producers

The primary industry impact of the alternatives is on the cost of data to support registrations. These costs are now borne primarily by the larger pesticide producing firms in the industry. As can be seen from Table X-1, firms with sales of less than $15 million (9 firms) accounted for only 5 percent of the total R&D expenditures in 1980. Similarly, they accounted for only 6 percent of personnel involved in pesticide R&D and 3 percent of the compounds screened for pesticidal potential. These data indicate that of the major producers (34 reporting in 1980), the smallest firms account for rather limited pesticide R&D efforts and therefore would tend to be less impacted with the regulatory options than would the larger firms.

The smallest category of major producers participating in the NACA survey (under $15 million in sales) however, had two of the seven new chemicals registered as pesticides in 1980. The regulatory options which affect the time to obtain registrations (such as alternative #4 which could lengthen the time to obtain registrations significantly) could adversely affect the smaller firms as well as the larger ones.

There are about 100 additional pesticide producing firms, generally smaller ones in terms of pesticide production, which probably are not covered by the NACA reports1/. The Agency has very limited economic profile information about these firms in particular. It is likely that cost impacts of the regulatory options on these smaller producers would be minimal. This would be true if the tendency for smaller firms to conduct relatively limited R&D applies to these firms as it does to the larger categories of firms in the industry. As with the larger producers, time delays in the registration process could adversely affect such firms.

1/ The names of firms responding to NACA's annual surveys are not identified.

Table X-1

Pesticide Research and Development Activities, by Size of Firm (Sales Volume), 1980

	1980 Sales Volume ($1,000,000)			
Item	Under $15	Between $15 to $100	Over $100	All Companies
Firms Reporting (No.)	9	12	13	34
Total Compounds Screened (No.)	2,540	11,365	75,438	89,343
Percent	3	13	85	100
R&D Expenditures ($1,000,000)				
New Product Development	14	53	186	253
Product Expansion	4	22	78	104
Reregistration & Product Defense	2	9	27	38
Total R&D Expenditures	20	84	291	395
Percent	5	21	74	100
Personnel in Pesticide R&D (No.)	360	1,244	4,226	5,830
Percent	6	21	72	100
New Product Registrations (No.)				
Full Registration	0	0	0	0
Conditional Registration	2	1	4	7

Source: NACA Report, 1981

As was discussed in Section IV, under the current program (Option #1), about 85 to 95 months of elapsed time are required to obtain a full commercial registration. Regulatory guidelines would reduce this time nominally by about 5 months on the average or by as much as 15 months over a significant number of cases depending on the firm's mode of operations and the types of registration involved. Self-certification #3 would reduce time to obtain registrations by 20 to 35 months. Provisional registration #5 would save a similar amount of time, but only for limited distribution of new chemicals, until all needed data were generated. These options (#3 and #5) do offer significant reductions in time required of up to two to three years. This could be particularly significant for smaller firms. On the other hand, comprehensive data requirements (Option #4) would increase time required for registration significantly over the current program, i.e., by 2 to 3 years. This would be significant to all firms, large and small.

B. Formulators

Formulators of pesticides can be classified into two types of firms.

a. Producer/formulators
b. Non-producing formulators

The pesticide producers as an aggregate of firms also account for most of the pesticide formulation. About three-fourths of the formulated pesticide products (80% according to one estimate) is accounted for by the formulation operations of the firms which also produce basic active ingredients of pesticides.

Implementation of any of the five options would tend to have limited impacts upon non-producing formulators because of the "horizontal line exemption". This exemption applies to the formulation of end-use products from other products which have registrations as specified in Subsection 3(c)(2)(D) of FIFRA. Specifically, that subsection of of FIFRA reads:

> "No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to -
>
> i) submit or cite data pertaining to the safety of such purchased product; or
>
> ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data."

to incur data costs on the active ingredients used in products which they formulate unless they are also the basic producers of the active ingredients. The price of the basic active ingredient or other manufacturing-use product with a registration by its producer, is assumed under the "horizontal line exemption" to reflect any data costs that would be passed on to the formulator by the producer. Most firms which are formulators (approximately 3,300 firms in the industry) would not be required to incur the substantial additional data costs on active ingredients under Option #4, comprehensive data requirements. Neither would they be positively impacted by self-certification which could reduce data costs dramatically on active ingredients. However, all of the formulating firms (whether or not they are also basic producers) would be directly impacted by data costs for formulated products (as opposed to the active ingredient) regardless of whether they were large or small firms. These costs are much less than the costs for active ingredients, and often are minimal or non-significant. Under the Agency proposal, regulatory requirements, data cost to the formulators on both active ingredients and formulated end-use products would remain unchanged and are generally minimal at this time under the current program in any case.

As with the basic producers, firms could be negatively or positively impacted by the time required for obtaining registrations of products under the various options. Under the Agency proposal, time requirements would decline to a degree whereas they could be increased significantly or decreased with the other options.

Formulators of small volume active ingredients could be negatively impacted particularly by Option #4, comprehensive data requirements, in instances where the basic producer chooses not to meet data requirements for the active ingredient or other manufacturing use product. In that instance, the firm would need to shift its formulating operations to other active ingredients and formulated products. As indicated in the analysis in Section VI of this report, the number of active ingredients to be lost by the Agency's proposal would be minimal, thus precluding major impacts of this type on formulators large or small.

C. Governmental Units

No significant impacts are anticipated on small governmental units from implementing the Agency's proposed option, regulatory requirements, or any of the other alternatives to the guidelines. Small governmental units, such as at the county, city or local level, are generally not involved in any of pesticide registration functions under FIFRA.

D. Pesticide Users

The proposed action by the Agency, regulatory requirements, would not produce a significant impact on users of pesticides, in general, either due to the cost of pesticide products or loss of current products. Pesticides are a relatively small component of cost for most firms in their operations regardless of the industry or the size of firm involved. Nevertheless, the pesticide using sectors are composed primarily of small business units or other entities as defined under the Regulatory Flexibility Act. There are more than a million small scale farms in the United States, 75 million households and millions of small businesses which utilize pesticides each year. These units would be affected to some degree by the regulatory options, particularly the most restrictive option, Comprehensive Data Requirements. The effects, even in those instances, would be minor in most cases. Some industries which use pesticides very intensively could be significantly impacted such as wood preserving firms where pesticides are a very significant part of their cost structure, i.e., 16% of total inputs. However, the Agency's proposal is to not significantly affect cost of pesticides or negatively affect the time it takes to obtain registrations.

In conclusion, the Agency's proposal to implement the regulatory requirements option (#2) rather than to maintain the current program as implemented nominally as the reference guidelines option (#1), would not produce a significant economic impact on a substantial number of small businesses or other entities. Although large numbers of such units are in affected industries, impacts would be insignificant, imperceptible in most instances. The major group affected is that of the pesticide producing industry which accounts for the bulk of data cost to support current registrations. Even this group would not be adversely affected by implementing the Agency's proposal.

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APPENDIX 1

Unit Cost Estimates

Chemistry Requirements
Product Chemistry
Unit Costs

Section	Cost Range in Dollars
Product Identity and Composition	
Product identity and disclosure of ingredients	Neg.[1]
Description of manufacturing process	500-2,000
Discussion of formation of impurities	1,000-2,000 MUP 100-200 FP
Analysis and Certification of Product Ingredient	
Analysis of product samples	5,000-7,000 MUP 1,000-2,000 FP
Certification of ingredient limits	100-200
Analytical methods	200,000-300,000 MUP
Biological Screening for Toxic Components	
Ames test	500-700
DNA repair in E. Coli	500-700
Prophage induction	750-1,000
Mitotic recombination	1,000-1,500
Sample analysis following positive results in battery of genotoxicity screening tests	20,000-30,000
Physical/Chemical Properities	2,000-3,000 MUP 1,500-2,000 FP
Other product chemistry requirements	
Submittal of samples	100-200[2]

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[1] Part of application, based on data developed in other sections.

[2] Samples other than of technical material may be required on a case-by-case basis.

Hazard Evaluation:
Wildlife and Aquatic Organisms
Unit Costs

Section	Cost Range in Dollars
Avian and Mammalian Testing	
Avian single-dose oral LD50	1,500-2,500
Avian dietary LC50	2,800-4,000[1]
Wild mammal toxicity	1,000-15,000[2]
Avian reproduction	25,000-30,000[1]
Simulated and actual field testing for mammals and birds	20,000-100,000[3]
Aquatic Organism Testing	
Acute toxicity test for freshwater fish	1,000-1,500[1]
Acute toxicity test for freshwater aquatic invetebrates	500-1,000
Acute toxicity test for estuarine and marine organisms	1,500-2,000
Fish early life-stage and aquatic invertebrate life-cycle	10,000-15,000
Life-cycle tests of fish	45,000-95,000
Aquatic organism accumulation	20,000-30,000
Simulated on actual field testing for aquatic organisms	100,000-250,000

1/ Two species.
2/ Depends on test species.
3/ Requirements range from small pen stu dies to large pen studies, and to field studies.

Hazard Evaluation:
Humans and Domestic Animals
Unit Costs

Section	Cost Range in Dollars
Acute Delayed Neurotoxicity MUP	9,000-12,000
Acute Dermal Toxicity MUP, FP	2,000-3,000
Acute Inhalation Toxicity MUP, FP	7,500-12,000
Acute Oral Toxicity MUP, FP	1,200-2,000
Repeated Dose Dermal MUP, FP Toxicity (21/28 Day)	28,000-32,000
Subchronic 90-Day Dermal FP, MUP Toxicity	60,000-90,000
Subchronic 90-Day Inhalation MUP Toxicity	60,000-120,000
Subchronic Neurotoxicity Study Tech	40,000-50,000
Subchronic Oral Toxicity Study Tech (2 species)	125,000-195,000
Dermal Sensitization Study MUP, FP	1,000-1,500
Primary Eye Irritation	750-1,000
Primary Dermal Irritation MUP, FP	500-700
Teratology (2 species) Tech	40,000-48,000
Reproduction and Fertility Tech	90,000-110,000
Chronic Toxicity Study Tech (2 species)	575,000-700,000 1/
Carcinogenicity Study Tech (2 species)	375,000-425,000 2/
Mutagenicity	40,000-60,000

1/ Assumes $375-450 thousand for rat.
$200-250 thousand for dog.

2/ Assumes $250-300 thousand for mouse
plus $125 thousand in addition
to cost of chronic study for rat.

Exposure Data Requirements:
Reentry Protection
Unit Cost

Section	Cost Range in Dollars
Description of Sites and Human Reentry Activitity	
Description and Selection of Human Activities	500-1,000
Sample Collection and Chemical Analyses of Residues and Volatiles	
Residue Dissipation Data on Surfaces	40,000-60,000
Dissipation of Airborne Pesticides	1/
Exposure Information	
Measurement of Respiratory Exposure	50,000-100,000
Measurement of Dermal Exposure	2/

1/ Combined with Section 163.132-1
2/ Combined with Section 163.133-2

Hazard Evaluation: Nontarget Insects Unit Costs

Section	Cost Range in Dollars
Nontarget Insect Testing - Pollinators	
Honey Bee Contact LD50	400-500
Honey Bee - Toxicity of Residues on Foliage	400-500
Wild Bees...Toxicity of Residues on Foliage	600-800
Honey Bee Subacute Feeding Study	10,000-15,000
Field Testing for Pollinators	4,000-6,000
Nontarget Insect Testing - Aquatic Insects	
Acute Toxicity to Aquatic Insects	800-1,000
Aquatic Insect Life-Cycle Study	10,000-14,000
Simulated or Actual Field Testing for Aquatic Insects	
Nontarget Insect Testing - Predators and Parasites [Reserved. Data requirements have not yet been specified]	

1/ Protocols and Agenc will be established upon consultation between registrant and Agency.

Chemistry Requirements:
Environmental Fate
Unit Costs

Section	Cost Range in Dollars
Degradation	
Hydrolysis	15,600-20,000
Photodegradation - Water	18,000-20,000
Photodegradation - Soil	15,000-17,500
Photodegradation - Air	18,000-25,000
Metabolism	
Aerobic Soil	25,000-35,000
Anaerobic Soil	1/
Anaerobic Aquatic	25,000-30,000
Aerobic Aquatic	25,000-30,000
Mobility	
Leaching	10,000-20,000
Volatility	8,500-12,000
Dissipation	
Field Dissipation/Terrestial	75,000-100,000
Field Dissipation/Aquatic	75,000-120,000
Field Dissipation/Special Aquatic	18,000-25,000
Field Dissipation/Forest	120,000-200,000
Dissipation/Combination/Tank Mix	25,000-35,000
Longer-Term Soil Dissipation	100,000-120,000
Accumulation	
Rotational Crops	40,000-60,000
Irrigated Crops	35,000-50,000
Accumulation in Fish	20,000-30,000
Accumulation/Aquatic Non-Targets	30,000-50,000

1/ Combined with aerobic metabolism.

APPENDIX 2

Benefit/Cost Sensitivity

Appendix Table 2-1
Benefit/Cost Sensitivity Analysis

	Alternative														
	#1			#2			#3			#4			#5		
	B	C	R	B	C	R	B	C	R	B	C	R	B	C	R
Industry Cost versus															
Environmental Emphasis	21.1	20.5	1.03	25.4	20.2	1.26	7.2	15.1	0.48	27.0	28.1	0.96	19.5	16.2	1.20
Middle-of-the-Road	21.3	20.5	1.04	24.2	20.2	1.20	10.0	15.1	0.66	25.0	28.1	0.89	19.5	16.3	1.20
Health Emphasis	20.3	20.5	0.99	24.6	20.2	1.22	9.2	15.1	0.61	27.0	28.1	0.96	19.0	16.3	1.17
Middle of the Road Cost versus															
Environmental Emphasis	21.1	20.5	1.03	25.4	20.0	1.27	7.2	15.6	0.46	27.0	26.8	1.01	19.5	17.1	1.14
Middle-of-the-Road	21.3	20.5	1.04	24.2	20.0	1.21	10.0	15.6	0.64	25.0	26.8	0.93	19.5	17.1	1.14
Health Emphasis	20.3	20.5	0.99	24.6	20.0	1.23	9.2	15.6	0.59	27.0	26.8	1.01	19.0	17.1	1.11
Program Cost versus															
Environmental Emphasis	21.1	20.2	1.04	25.4	19.8	1.28	7.2	16.5	0.44	27.0	25.4	1.06	19.5	18.0	1.08
Middle-of-the-Road	21.3	20.2	1.05	24.2	19.8	1.22	10.0	16.5	0.61	25.0	25.4	0.98	19.5	18.0	1.08
Health Emphasis	20.3	20.2	1.01	24.6	19.8	1.24	9.2	16.5	0.56	27.0	25.4	1.06	19.0	18.0	1.06

C = Cost Rating
B = Benefit Rating

NOTE: For factor weightings, used in analysis, see Appendix Tables 2-2 and 2-3.

Appendix Table 2-2
Weightings Used For Benefit Factors in Benefit/Cost Sensitivity Analysis

Benefit Factors:	Program Policy Emphasis Environmental Emphasis	 Middle-of-the-Road	 Health Emphasis
Program Benefits-			
Certainty of Registerability of Products	5	10	5
Time to Obtain Registration	5	10	5
Coordination with Other Programs	5	10	5
Health Effect-			
Acute	10	10	10
Chronic	40	50	65
Environmental Effects	35	10	10
	100	100	100

Appendix Table 2-3
Weightings Used for Cost Factors in Benefit/Cost Ratio Sensitivity Analysis

Cost Factors:	Program Policy Emphasis: Industry Oriented	Program Policy Emphasis: Middle-of-the-Road	Program Policy Emphasis: Program Cost Emphasis
Program Costs	20	35	50
Industry Compliance Costs	45	30	20
Producer Structure	5	5	5
Producer Competitive Behavior	5	5	5
Producer Performance	5	5	5
Small Firm Impacts	5	5	5
Pesticide Users Costs (Ag.)	0	0	0
Pesticide Users Costs (Non-Ag.)	0	0	0
Loss of Products	5	5	5
Major Ag. Commodity/ Food Prices	10	10	5
Other Prices	0	0	0
Employment	0	0	0
	100	100	100

APPENDIX 3

Cost-Effectiveness Analysis in Reducing Hazards

COST-EFFECTIVENESS ANALYSIS IN REDUCING HAZARDS

A. Human Health

1. Willingness-to-Pay Approach

Data requirements pertaining only to human hazard total about $76 million.1/ If one assumes that the WTP value of a life is $300,000 as has been estimated in some studies, then the information derived from $65 million worth of testing must yield 253 lives saved to be cost effective. If one accepts a higher value of $1.5 million per life, then 51 lives need to be saved in order for the testing to be cost effective. At the extreme, if one accepts a value of $600 million per life, then less than one life need be saved in order for the tests to be cost effective.

It can be seen from these estimates that the cost effectiveness of data requirements is highly sensitive to the value placed on lives saved. However, it seems reasonable to assert that the hazard testing data would be cost effective if they are expected to save at least 150-200 lives per year by not allowing dangerous substances to be registered for pesticidal use.

2. Human Capital Approach

In Section IV, the human capital approach (HC) was used to estimate the cost to society of poisonings and cancer. If we compare these estimates to the cost of testing, we can determine the number of effects which must be avoided to justify the testing requirements.

a.) Acute Testing

The acute testing requirements would cost approximately $3.3 million annually. On average, each death due to pesticide poisoning costs $112,000 and each non-fatal poisoning costs $200.

In order to make the testing requirements cost effecitve and if one accepts these HC units costs, 30 fatal poisonings or 16,500 non-fatal poisonings, or some combination of the two would have to be avoided annually.

b.) Chronic Testing

Reliable estimates of HC unit costs could not be developed for all chronic effects caused by pesticides. However, a unit cost for cancer of $52,000 was estimated. In order to make the annual chronic testing cost of $61.9 million effective, approximately 1,190 cases of cancer would have to be avoided annually.

1/ This total is an approximate long-term annual average based on the direct cost estimates developed for Option #2 in Section V of this report. The assumptions made are 25 Registration Standards developed each year and Data Call-In in effect. The estimate of $1.4-4.2 million for ecological testing presented later has the same basis.

If we go one step further and adopt the assumption that other chronic effects, which may be in part caused by pesticides, occur at the same rate as cancer cases, we can develop hypothetical unit costs for the remaining effects. It should be noted that this assumption is very tenuous and allows us to develop estimates which are extremely crude at best.

Table 1 presents the unit costs derived using the above assumption. These units costs could then be used to determine the threshhold levels of each effect or combination of effects which must be avoided to make the chronic testing portion of the regulatory requirements cost effective. Supportable estimates cannot be made as to the current underlying actual rates of chronic health effects resulting from pesticides nor what the rate might be under the alternative regulatory approaches. Thus, true cost-effectiveness measure cannot be estimated.

3. Effectiveness of Chronic Tests on a Per Chemical Basis

This section will explore the question of effectiveness of chronic studies. That is, for those chemicals that will be subjected to chronic studies (particularly onco studies), what is the relative effectiveness among the alternative approached?

After reviewing the Agency RPAR record, the findings were that of about 85 chemicals referred to the RPAR review process, 23 chemicals were issued an RPAR. Of these 23 chemicals, 17 had an oncogencity trigger. If one assumes that these 17 chemicals suspected of being oncogens under RPAR comprise all the oncogens in the 85 chemicals referred and that for all 600 currently registered chemicals this same rate (17 out of 85), holds then up to 20% of all pesticides currently registered might be oncogens. On the otherhand, if the 17 suspected oncogens comprise all oncogens out of the 600 currently registered chemicals, the rate would be reduced to about 3%. Furthermore, the average suspected oncogen reviewed in the RPAR process was estimated to create at lifetime risk of $1x10^{-6}$ or about one case per million persons exposed. From these assumptions, we can deduce that of 15 new chemicals offered for registration annually, 0.45 to 3.0 or a rounded average of 2 oncogens might occur. The scientific basis for projecting the expected rates of adverse chronic health effects under the five regulatory options is tenuous. The best that can be done is to make crude estimates of the relative outcomes under the 5 approaches.

Generally, the higher the proportion of chemicals tested the higher the probability of identifying suspected oncogens and hence regulating in a manner that would avoid the occurence of the highest number of potential cases. Option 4, comprehensive requirements where all chemicals are tested, would thus result in the outcome where virtually all oncogens would be identified. Conversely, Option 3,

Table 1

Estimated Unit Costs for Selected Chronic Effects

Disease Category	Unit Cost[a] ($)
Complications of pregnancy, childbirth, and puerperium	8,636.
Congenital anomalies	3,463.
Certain causes of perinatal morbidity and mortality	2,356.

[a] For a complete discussion of estimate derivation see the detailed cost-benefit report.

self-certification would result in the testing of the fewest chemicals and hence would be the least likely to result in cancer cases avoided. Options 1 and 2, reference guidelines and regulatory requirements respectively, would result in testing of not all chemicals but all where potential exposure is of concern. Hence, these options would result in avoiding almost as many cancer cases as Option 1. Regulatory requirements would be slightly more effective than reference guidelines since testing would be done using consistent methods. Option 5, provisional registration, would appear to fall somewhere below Options 1 and 2 since some limited exposure to an unknown oncogen might occur before the result of the animal feeding studies indicated the potential hazard. Option 5 would also likely be a significant improvement over self-certification in terms of potential ill effects avoided. Table 2 summarizes this ordering of alternative approaches.

A similar relative ranking of the alternative approaches can be made for chronic health effects other than cancer. There is even a smaller amount of information on the rate that these other chronic effects might be triggered as a result of pesticide exposure.

Table 2 also provides estimates that on an annual basis $10-30 million would be expended on oncogenicity/chronic effects testing depending on the alternative approach selected. These figures include a proportion of the cost of data generated by product and environmental chemistry necessary to support a cancer risk assessment. To the testing costs would be added a share of the program resources used in regulating pesticides (reviews and decision-making support) as potential carcinogens. The total annual projected costs of discovering and regulating potential pesticide carcinogens is shown in Table 2 to be $21-42 million depending on the approach taken.

If one puts aside the controversial subject of discounting future deaths, the conclusion drawn is that chronic testing is highly cost effective. Alternative 2 (regulatory requirements) provides the most favorable outcome of the alternative approaches analyzed. As one moves to the case of a more potent carcinogen, the argument becomes even stronger. For a chemical unknowingly approved with a risk factor of 10^{-5} (from 10^{-6}), the number of cancer cases avoided would be 10 times higher and the unit costs of cases avoided inversely proportionately less.

B. Environmental Hazards

While it is not possible to estimate an average unit cost of environmental effects, it has been estimated earlier in the document that closing the Central and Pacific Flyway to waterfowl hunting would cost $47.6 million annually. While this is a relatively large environmental effect, it demonstrates the high value society places on environmental and recreational resources relative to the $1.4-$4.2 million annual cost of the ecological testing portion of the guidelines.

Table 2. Relative Cost-Effectiveness Measures of Alternative Approaches with Respect to Oncogenicity

	Option				
	Reference Guidelines	Regulatory Requirements	Self-Certification	Comprehensive Requirements	Provisional Registration
	- - - - - - - - - - - - - - - $ Millions (Annual)- - - - - - - - - - - - - -				
Oncogenicity Effects					
-Testing Costs	21	21	10	30	16
-Other Costs (Programs)	12	12	11	12	13
-Total Costs	33	33	21	42	29
Relative Ordering for Potential Cases Avoided a/	2	2	5	1	4

a/ Options are ranked in descending order, i.e. 1 = most cases avoided and 5 = least cases avoided.

In order to get a perspective on the magnitude of the benefits necessary to make a social investment in non-target species and attendant environmental fate and product chemistry testing worthwhile, assume that waterfowl hunting days are representative of all of the different types of ecological benefits to society. As indicated in Table 3, these tests are anticipated to cost between $1.4 and $4.2 million per annum under the regulatory requirements (under the reference guidelines and provisional registration options as well). At a social value of $9 per day, the non-target species and attendant tests only have to preserve or generate between 156,000 to 467,000 days of waterfowl hunting before they have paid for themselves. This represents a very small proportion, 1.2 to 3.6 percent, of the total stock of waterfowl hunting days Americans enjoy nationally each year. On the other hand, the comprehensive data requirements option, which would probably cost from $13.8 to $15.2 million for these tests, would have to generate or preserve many more waterfowl hunting days, some 1,530,000 - 1,690,000, or 11.8 to 13 percent of the total stock. In contrast to this, the self-certification option with testing costs of $0.8 to $2.3 million requires generation or preservation of only 89,000 to 256,000 hunting days before it has paid for itself. This is a 0.6 to 1.9 percent change in the total of waterfowl hunting days.

Table 3 Annual Implicit Value of Non-Target Species Testing

	Option				
	Reference Guidelines	Regulatory Requirements	Self-Certification	Comprehensive Data Requirements	Provisional Registration
Cost of Non-Target Species Testing (Subpart E) and Attendant Environmental Fate and Product Chemistry Tests	\$1.4 mil- \$4.2 mil	\$1.4 mil- \$4.2 mil	\$0.8 mil- \$2.3 mil	\$13.8 mil- \$15.2 mil	\$1.4 mil- \$4.2 mil
Value of a Waterfowl Hunting Day	\$9	\$9	\$9	\$9	\$9
Savings in Number of Waterfowl Hunting Days Required to Offset These Costs	.156 mil- .467 mil	.156 mil- .467 mil	.089 mil- .256 mil	1.53 mil- 1.69 mil	.156 mil- .467 mil
Percent These Represent of Total Waterfowl Hunting Days in US (12.93 mil per annum*)	1.2 - 3.6	1.2 - 3.6	0.6 - 1.9	11.8 - 13.0	1.2 - 3.6

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*G.M. Brown, Jr., J.J. Charbonneau and M. J. May, "The Value of Wildlife Estimated by the Hedonic Approach" Working Paper #6, Division of Program Plans, U.S. Fish and Wildlife Services, March, 1979, pg. 23.

**Office of Migratory Bird Management, Annual Migratory Bird Hunting Regulations: Final Regulatory Impact Analysis, Fish and Wildlife Service, U.S. Department of the Interior, June, 1981, pp. 29-4.